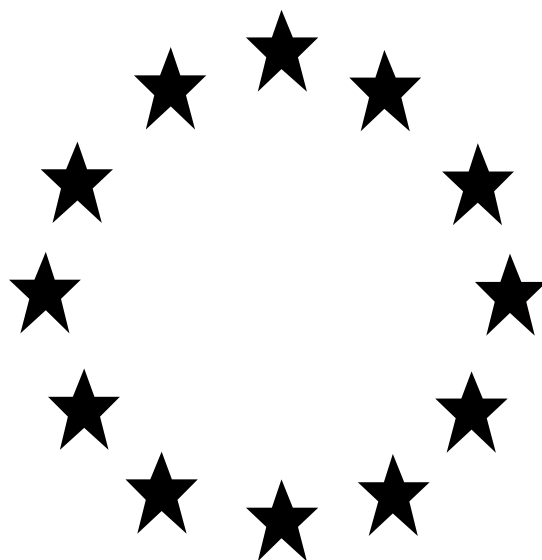




# **Draft Assessment Report (DAR)**

**- public version -**

**Initial risk assessment provided by the rapporteur Member State  
Portugal for the existing active substance**

**CALCIUM CARBIDE**

**of the fourth stage of the review programme  
referred to in Article 8(2) of Council Directive 91/414/EEC**

**Volume 1**

**August 2008**

PORTUGAL

MINISTÉRIO DA AGRICULTURA DO DESENVOLVIMENTO RURAL E DAS PESCAS  
DIRECÇÃO-GERAL DE AGRICULTURA E DESENVOLVIMENTO RURAL

**Report prepared in the context of the inclusion of calcium carbide  
in Annex I of the Council Directive 91/414/EEC**

**CALCIUM CARBIDE**

**Volume 1**

**Report and proposed decision**

**2007**

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## **CALCIUM CARBIDE**

### **LEVEL 1**

Statement of subject matter and purpose for which the monograph was prepared

## **1 Statement of subject matter and purpose for which the monograph was prepared**

### **1.1 Purpose for which the monograph was prepared**

This monograph was prepared to in view of the request for the first inclusion of the existing active substance Calcium carbide in Annex I of the Council Directive 91/414/EEC, in the scope of Commission Regulation (EC) No 1112/2002, amended by Commission Regulation (EC) No 2229/2004 (Fourth stage, Part A, Group 6.1), made by the Task Force Calcium Carbide.

The Annex IIA of Calcium carbide is supported by an Annex IIIA for “PRONTOX Wühlmausgas” that is formulated as Calcium carbide 800g/kg GE.

### **1.2 Summary and assessment of information relating to the collective provision of dossiers**

Although the notification was made by Chemische Fabrik Wülfel GmbH & Co. KG, the submission of this dossier has been conducted by Chemische Fabrik Wülfel GmbH & Co. KG (Hannover) and Detia Freyberg GmbH (Laudenbach) collectively.

A letter of agreement for the “Task Force Calcium Carbide” is included in document B of the dossier.

### **1.3 Identity of the active substance**

A dossier was submitted for the evaluation of the active substance calcium carbide.

For the proposed use (repellent), technical calcium carbide needs to contain calcium phosphide (0.02%w/w) for the production of phosphine in the presence of moisture. Phosphine has a garlic odour and in fact it is the repellent active substance.

Experts present in the PRAPeR 06 Meeting, organised by EFSA, agreed that RMS should evaluate and report the real active substance calcium phosphide. Due to the fact that phosphine is a very toxic gas, it was also agreed by those experts to set a range in the specification (minimum and maximum purity) of calcium phosphide, to prevent having a different function for this active substance, e.g. rodenticide, if the content of calcium phosphide present in calcium carbide would be much higher.

However, Commission decided that the DAR should be finalised for the calcium carbide as it was included in the 4<sup>th</sup> stage review programme and is authorised for use in that form.

Hereafter calcium carbide should be regarded as a technical with a very low content of calcium phosphide.

#### **1.3.1 Applicant (name, address, contact, telephone and telefax numbers)**

Task Force Calcium carbide:

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### 1.3.2 Common name and synonyms

Calcium phosphide.

Calcium carbide (calcium acetylide)

### 1.3.3 Chemical name

IUPAC Calcium phosphide (Tricalcium diphosphide)

Calcium carbide (calcium acetylide)

CA Calcium phosphide

Calcium carbide

### 1.3.4 Manufacturer's development code number

Not available.

### 1.3.5 CAS, EEC and CIPAC numbers

Calcium phosphide

Calcium carbide

CAS: 1305-99-3

CAS: 75-20-7

EC: 215-142-0

EINECS: 200-848-3

### 1.3.6 Molecular and structural formulae, molecular mass

Calcium phosphide

Calcium carbide

Molecular formula:  $\text{Ca}_3\text{P}_2$

Molecular formula:  $\text{CaC}_2$

Structural formula:

Structural formula:

$\text{P}^{3-}$

$\text{Ca}^{++} \text{Ca}^{++} \text{P}^{3-}$

$\text{Ca}^{++} \text{C} \equiv \text{C}^-$

$\text{Ca}^{++}$

Molecular mass: 182.18 g/mol

Molecular mass: 64.10 g/mol

### **1.3.7 Manufacturer or manufacturers of the active substance**

Confidential information, see Volume 4 / Annex C.

### **1.3.8 Method or methods of manufacture**

Confidential information, see Volume 4 / Annex C.

### **1.3.9 Specification of purity of the active substance**

RMS proposal:

Calcium phosphide 0.08 - 0.52 g/kg

Calcium carbide 765 – 810 g/kg

### **1.3.10 Identity of isomers, impurities and additives**

Confidential information, see Volume 4 / Annex C.

### **1.3.11 Analytical profile of batches**

Confidential information, see Volume 4 / Annex C.

## **1.4 Identity of the plant protection product**

### **1.4.1 Current, former and proposed trade names and development code numbers**

Trade name: PRONTOX Wülmausgas

Development code number:

PRONTOX Wülmausgas is the technical product sold unformulated.

### **1.4.2 Manufacturer or manufacturers of the plant protection product**

Confidential information, see Volume 4 / Annex C.

### **1.4.3 Type of the preparation and code**

Proposed by notifier: Technical product (TK)

Proposed by RMS: Gas generating product (GE)

### **1.4.4 Function**

Repellent

## 1.4.5 Composition of the preparation

|                                                     |                                                             | [%w/w]       |
|-----------------------------------------------------|-------------------------------------------------------------|--------------|
| Typical content of the technical active substance   | (typ. purity 0.025% calcium phosphide, 80% calcium carbide) | 100          |
| Declared (nominal) content of pure active substance | Calcium phosphide                                           | 0.025 – 0.05 |
|                                                     | Calcium carbide                                             | 80           |

## 1.5 Uses of the plant protection product

### 1.5.1 Field of use

Calcium carbide formulated as PRONTOX-vole gas (PRONTOX Wühlmausgas) is a gas generating product to be used as repellent against voles and moles in meadows, fruit, vegetable, field and ornamental cultivation and in house and allotment areas. The solid product is to be placed in the holes made by the pests.

### 1.5.2 Effects on harmful organisms

For the proposed use (repellent), technical calcium carbide needs to contain calcium phosphide (0.02%w/w) for the production of phosphine in the presence of moisture. Phosphine has a garlic odour and is in fact the repellent active substance.

### 1.5.3 Summary of intended uses

The intended uses are summarised in Table 1.5-1.

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Table 1.5-1 – Summary of intended uses

| Crop and/or situation<br>(a)                                                                                        | Member State or Country   | Product name        | F G or I<br>(b) | Pests or Group of pests controlled<br>(c)                                  | Preparation   |                          | Application          |                              |                        |                                     | Application rate per treatment<br>(for explanation see the text in front of this section) |                         |                                                                                             | PHI (days)<br>(m) | Remarks |
|---------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------|-----------------|----------------------------------------------------------------------------|---------------|--------------------------|----------------------|------------------------------|------------------------|-------------------------------------|-------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------|-------------------|---------|
|                                                                                                                     |                           |                     |                 |                                                                            | Type<br>(d-f) | Conc. of as<br>(i)       | method kind<br>(f-h) | growth stage & season<br>(j) | number min/ max<br>(k) | interval between applications (min) | g as/hL<br>min – max<br>(l)                                                               | water L/ha<br>min – max | g as/ha<br>min – max<br>(l)                                                                 |                   |         |
| Vegetables (NNNWW)<br>Fruit (NNNOO)<br>Ornamental plants (NNNZZ)<br>Agricultural crops (NNNAC)<br>Grassland (NNNFW) | Germany (Northern Europe) | PRONTOX Wühlmausgas | F               | <i>Arvicola terrestris</i> (ARVCTE),<br><br><i>Talpa europaea</i> (TALPEU) | GE            | 800 g/kg Calcium carbide | covered application  | all stages                   | if/ when required      | without waiting-time                | not applicable                                                                            | not applicable          | 4-8g/hole<br><br>16g/hole<br><br>(2-8kg/ha for a maximum infestation level of 500 holes/ha) | not required      |         |

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).</p> <p>(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated</p> | <p>(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). <b>In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialdicarb-isopropyl).</b></p> <p>(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)</p> <p>(m) PHI - minimum pre-harvest interval</p> |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

#### 1.5.4 Information on authorisations in EU Member States

##### Germany

Agricultural crops, fruit, vegetable and ornamental growing, grassland, house and allotment areas:

*Arvicola terrestris*, *Talpa europaea*;

5-10g PPP/ hole (*Arvicola terrestris*)

20g PPP/ hole ( *Talpa europaea*)

Application if required

## **CALCIUM CARBIDE**

### **LEVEL 2**

Reasoned statement of the overall conclusions drawn by the Rapporteur  
Member State

## 2 Reasoned statement of the overall conclusions drawn by the Rapporteur Member State

### 2.1.1 Identity

Calcium carbide is a repellent that reacts in contact with water or moisture to produce acetylene, small quantities of phosphine and calcium hydroxide. The repellent action of technical calcium carbide is based on the garlic-like odour of phosphine.

The presentation of the dossier was based on calcium carbide as active substance; therefore data on the real active substance, calcium phosphide, was submitted regarding as an impurity. However for the intended use (as repellent) a technical calcium phosphide does not exist in the sense of Directive 91/414/EEC, as the impurity level of calcium phosphide present in technical calcium carbide is enough to act as repellent. Evaluation was performed taking in consideration that calcium carbide is a technical with a very low content of calcium phosphide

Technical specifications were submitted for each manufacturer, based on non-GLP analysis of representative batches of the industrial scale. No proposal was submitted for the minimum content of active substance calcium phosphide.

Taking in account the two analytical profiles, calcium phosphide has a range content of 0.08 – 0.52 g/kg and calcium carbide a range content of 765 – 810 g/kg (RMS proposal). A maximum content for calcium phosphide is proposed, based on the maximum content found in the two analytical profiles to prevent having a different function for this active substance (e.g. rodenticide).

Equivalence of the two technical specifications cannot be assessed by tier I approach (Guidance document Sanco/10597/2003) due to an unacceptable increase of a certified limit of a non-relevant impurity. Under tier II approach, this impurity is of no toxicological concern, and both sources of calcium carbide are considered equivalent from the toxicological and ecotoxicological point of view.

The representative formulation, PRONTOX Wülmausgas, is the technical containing 0.025% - 0.05% of calcium phosphide and 80% of calcium carbide.

### 2.1.2 Physical and chemical properties

No information was submitted on purified calcium phosphide.

For inorganic substances that in contact with water liberate toxic and extremely flammable gases, only vapour pressure and appearance should be set according to data requirements in the context of the 4th stage of the review programme. Through International Chemical Safety cards calcium phosphide is a red-brown crystalline powder or grey lumps, stable in the dry state but reacts violently with acids, water or moist air to produce phosphine. It has a melting point of 1600 °C, with negligible vapour pressure in the dry state. Due to its chemical structure calcium phosphide is expected to have a very low solubility in organic solvents.

Technical calcium carbide presents in the form of grey granules with garlic like odour. It has a melting point of 1845 °C, it is non-volatile, stable when dry, but decomposes slowly in moist air liberating acetylene and phosphine. It is neither explosive nor oxidising. For this type of product flammability should be assessed with EEC A12 method (contact with water). According to European Chemical Substances Information System this product is classified as highly flammable.

The representative formulation, PRONTOX Wülmausgas, is the technical containing 0.025% - 0.05% of calcium phosphide and 80% of calcium carbide, it is a gas generating product (GE). Its stability depends on the packaging impermeability to avoid reactions with humidity of the air. Since the dossier was based on calcium carbide as active substance a study on storage stability should be submitted with control analysis of calcium phosphide. The product is neither explosive nor

oxidising but it is classified as a highly flammable substance. Its technical properties indicate no particular problems when used as recommended.

## **2.1.3 Details of uses and further information**

### **2.1.3.1 Details of uses**

The intended uses of calcium carbide are summarised in Level 1 – point 1.5.3. The summary of authorisations in the EU Member States as stated by the notifier is reported in Level 1 – point 1.5.4.

Calcium carbide formulated as PRONTOX-vole gas (PRONTOX Wühlmausgas) is a gas generating product to be used as repellent against voles and moles in meadows, fruit, vegetable, field and ornamental cultivation and in house and allotment areas. The solid product is to be placed in the holes made by the pests.

For the proposed use (repellent), technical calcium carbide needs to contain calcium phosphide (0.02%w/w) for the production of phosphine in the presence of moisture. Phosphine has a garlic odour and is in fact the repellent active substance.

### **2.1.3.2 Further information**

No information was submitted for calcium phosphide.

Material Safety Data Sheet according 91/155/EEC for PRONTOX Wülmausgas was submitted.

As the product in contact with water liberates extremely flammable gases, its stability depends on the impermeability of the packaging, calcium carbide is stored in sealed-joint pack with tear-off top and inner packaging to exclude that water or humid air can penetrate into the steel container.

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## 2.1.4 Classification and labelling

### 2.1.4.1 Proposals for the classification and labelling of the active substance

**Calcium phosphide** based on European Chemical Bureau – European Chemical Substances Information System (ECB-ESIS) is classified as follows:

|                       |        |                                                                                                                                               |
|-----------------------|--------|-----------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard symbols:       | F      | Highly flammable                                                                                                                              |
|                       | T+     | Very toxic                                                                                                                                    |
|                       | N      | Dangerous for the environment                                                                                                                 |
| Indication of danger: |        | F: Highly flammable                                                                                                                           |
|                       |        | T+: Very toxic                                                                                                                                |
|                       |        | N: Dangerous for the environment                                                                                                              |
| Risk phrases:         | R15/29 | Contact with water liberates toxic, extremely flammable gas                                                                                   |
|                       | R28    | Very toxic if swallowed                                                                                                                       |
|                       | R50    | Very toxic to aquatic organisms                                                                                                               |
| Safety phrases:       | S1/2   | Keep locked up and out of the reach of children                                                                                               |
|                       | S22    | Do not breathe dust                                                                                                                           |
|                       | S43    | In case of fire, use... (indicate in the space the precise type of fire-fighting equipment. If water increases risk, add – “Never use water”) |
|                       | S45    | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)                                    |
|                       | S61    | Avoid release to the environment. Refer to special instructions/Safety data sheets)                                                           |

**Calcium carbide** is classified in Annex I of Council Directive 67/548/EEC (19<sup>th</sup> ATP) as **F** (highly flammable), **R15, S8, S43** (Calcium carbide liberates acetylene in contact with water in hazardous quantities. Acetylene is an extremely flammable gas).

The manufacturer proposes to additionally classify the a.s. as Xi (irritant); risk phrases R37/38 (irritating to respiratory system and skin), and R41 (risk of serious damage to eyes).

However, RMS proposes to classify calcium carbide as **C (corrosive)**, **R35 (causes severe burns)** due to its high pH in contact with water (see point B.6.2.4), and as demonstrated by the several acute toxicity studies that were not performed considering this property of the a.s. (see point B.6.2.1 to B.6.2.6). The proposal is also based on human experience (see medical data, point B.6.9.1 and B.6.9.4) where it is shown that, although dry calcium carbide in contact with skin may cause “only” dermatitis, contact with moist skin -and mucous membranes- leads to ulceration and scarring or full thickness burns. **R37 (irritating to respiratory system)** is based on human data (see medical data, point B.6.9.1, B.6.9.2 and B.6.9.4).

RMS proposal:

|                 |           |                                                                                                            |
|-----------------|-----------|------------------------------------------------------------------------------------------------------------|
| Hazard symbols: | F         | Highly flammable                                                                                           |
|                 | C         | Corrosive                                                                                                  |
|                 | N         | Dangerous for the environment                                                                              |
| Risk phrases:   | R15       | Contact with water liberates extremely flammable gases.                                                    |
|                 | R35       | Causes severe burns.                                                                                       |
|                 | R37       | Irritating to respiratory system.                                                                          |
|                 | R51/53    | Toxic to Aquatic organisms. May cause long term adverse effects in the aquatic environment.                |
| Safety phrases: | S1/2      | Keep locked up and out of the reach of children                                                            |
|                 | S8        | Keep container dry.                                                                                        |
|                 | S26       | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.              |
|                 | S36/37/39 | Wear suitable protective clothing, gloves and eye/face protection.                                         |
|                 | S43       | In case of fire, use sand. Never use water.                                                                |
|                 | S45       | In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible) |
|                 | S60       | This material and its container must be disposed of as hazardous waste.                                    |
|                 | S61       | Avoid release to the environment. Refer to special instructions/Safety data sheets)                        |

#### 2.1.4.2 Proposals for the classification and labelling of preparations

Calcium carbide technical is identical to the commercial product PRONTOX Wühlmausgas. As the preparation is the same as the active substance, proposal for classification is the same as referred above (see point 2.1.4.1 above).

## 2.2 Methods of analysis

### 2.2.1 Analytical methods for analysis of the active substance as manufactured

Unsufficient data was provided to allow the acceptability of the methods for determination of calcium phosphide, calcium carbide and impurities in the technical calcium carbide.

Full description of the methods and correspondent validation data were not submitted. Notifier stands that section 2 is not required according to requirements for substances listed in Part A of the Commission Regulation guidance document (Sanco/10393/2004-rev.4 08/10/04), although for identity methods are required.

### 2.2.2 Analytical methods for formulation analysis

PRONTOX Wülmausgas is the technical calcium carbide sold unformulated (see 2.2.1).

### 2.2.3 Analytical methods for residues analysis

Relevant residues of calcium phosphide or calcium carbide in food of plant and animal origin and in the environmental compartments are not expected to occur. No residue definition is proposed; therefore analytical methods for residues analysis are not required.

Methods for the determination of residues in body fluids and tissues are not required since relevant residues of calcium phosphide or calcium carbide are not expected to occur due to their degradation to phosphine and acetylene respectively.

## 2.3 Impact on human and animal health

### 2.3.1 Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products

#### Toxicokinetic

Studies on the absorption, distribution, metabolism and excretion of calcium carbide in mammals do not exist.

Detailed investigations of calcium carbide metabolism based on the hydrolysis to calcium hydroxide and acetylene were not considered to be required, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent.

In the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal's burrows where it is decomposed to calcium hydroxide and acetylene by ground humidity. Additionally, odour-intensive phosphine gas arises from hydrolysis of the very small amounts of calcium phosphide present on the technical material.

In the prescribed use of calcium carbide, there is no contact with plant roots above the soil surface. The uptake of acetylene by plant roots cannot be demonstrated due to the high volatility of acetylene. According to "American Chemistry Council, HPV Challenge, Acetylene Panel, Report n. °201-15005A of December 30, 2003", acetylene is a gas, and 99.9% partitions to the air, 0.104% partitions to the water, 0.0101% partitions to the soil and 0.000177 partitions to the sediment were estimated.

The calcium hydroxide remaining in the ground binds with carbon dioxide in the air and forms calcium bicarbonate in the first stage, which later partly changes into calcium carbonate. Both substances do not possess any toxic properties. From the facts presented, it follows that the calcium carbide itself, as well as its decomposition product acetylene, calcium hydroxide and phosphine do not enter into the food chain.

Besides this, calcium hydroxide and calcium carbides' impurity calcium oxide are food additives specified by EC regulations (SCF-Scientific Committee for Food) and by FAO/WHO (JECFA – Joint Expert Committee on Food Additives). An ADI (Acceptable Daily Intake) is not specified based on the fact that these substances are normal constituents of the diet and can not be distinguished from the same ions already present in food from other sources when used according to good manufacturing practice.

#### Acute toxicity

Technical calcium carbide and his main impurity calcium oxide are dusty alkaline materials. In contact with moist skin and mucous membranes they develop calcium hydroxide, a middle-strong alkaline substance. Calcium carbide/calcium oxide dust irritates the eyes and upper respiratory tract. The irritant effects are probably due primarily to its alkalinity, but dehydrating and thermal effects

also may be contributing factors.

On the basis of the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals. Symptoms upon ingestion of calcium carbide are abdominal cramps, burning sensation, vomiting and weakness from the open literature. No classification regarding the acute oral, dermal and inhalation toxicity of calcium carbide is required according to Annex I of Directive 67/548/EEC and its amendments.

Dry calcium carbide in contact with skin may cause dermatitis. Contact with moist skin and mucous membranes leads to ulceration and scarring. A peculiar type of melanoderma with strong hyperpigmentation and numerous telangiectases is often observed. Burns caused by hot calcium carbide are common. The tissues are generally damaged in depths of 1 to 5 mm; the burns evolve very slowly, are difficult to treat, and often require excision.

Persons exposed to calcium carbide frequently suffer from cheilitis characterized by dryness, swelling and hyperaemia of the lips, intense desquamation, and deep radial fissures; erosive lesions with tendency to suppuration can be observed in the mouth angles. Workers with a long professional history often suffer from nail lesions –that is occupational onychia and paronychia.

Calcium carbide is particularly hazardous to the eyes. Workers with a long professional history often show eye lesions with pronounced hyperaemia of the lids and conjunctiva, often accompanied by mucopurulent secretions. In heavy cases the sensitivity of the conjunctiva and cornea is strongly reduced. While the keratitis and keratoconjunctivitis evolve first without symptoms, they may later degenerate into corneal opacities. Symptoms of short-term exposure of the eyes are redness, pain, blurred vision, severe deep burns.

Based on the composition of the test substance and available results on the possible skin sensitizing properties its components, it was anticipated that the test substance is not a skin sensitizer.

#### Toxicity of metabolites

##### *Calcium hydroxide*

The LD<sub>50</sub> of the metabolite calcium hydroxide is reported from the literature to be about 7300 mg/kg bw in rats and mice. Because of its low solubility and apparently slow penetration into tissues, its aqueous solutions are not reported to be corrosive. However, inhalation of calcium hydroxide causes burning sensation and cough. It produces severe eye irritation and has been reported to cause dermatitis in humans; it is a skin and mucous membrane irritant.

##### *Acetylene*

In humans acetylene is not acutely toxic below its lower explosive limit of 2.5 % (25'000 ppm). It has been established in the literature that acetylene behaves in mammalian systems primarily as a central nervous depressant and asphyxiant at high dose levels (100'000 ppm in air or above). It produces varying degrees of temporary and reversible narcosis when administered with oxygen in concentrations of 100'000 ppm (10% in air) and higher. Repeated exposures of rats, mice, guinea pigs, rabbits and dogs to concentrations up to 800'000 ppm showed no evidence of cellular injury to the parenchymatous cells of the heart, lungs, liver, kidneys, or spleen.

Limited data reported in the literature indicate that Acetylene is rapidly adsorbed and eliminated unchanged in the body. The blood-gas partition coefficient of acetylene indicates that the material has a greater propensity to be removed from blood than to be retained in it. The lungs rapidly excrete acetylene. The gas also diffuses rapidly from the peritoneal and pleural cavities and diffuses through the skin. Therefore, acetylene is unlikely to persist in the body, even after repeated exposure to low concentrations that may be encountered in the workplace. Overall, the data support a rat LC<sub>50</sub> > 100'000 ppm.

### *Phosphine*

Actually, the active substance of technical calcium carbide is calcium phosphide contained in minor quantities of 0.025 % w/w or 0.25g calcium phosphide/kg calcium carbide.

In the mode of application of calcium carbide this small quantity is released over several hours, in consequence, according to the Notifier, the concentration of phosphine is always in a non-toxic range but is attaining the threshold value of smelling (0.02 ppm).

### *Medical data*

All workers involved with the production of calcium carbide are regularly monitored at intervals of 12 months by occupational medical inspections according to the requirements of the German national regulations on hazardous substances (Gefahrstoffverordnung (GefStoffV), Annex III No. 2, particle-shaped hazardous substances). In addition to this, special comprehensive health checkups are conducted in intervals of 36 months according to recommendation no. 26 (relevant where protective respiratory devices are used) of the professional trade association (Berufsgenossenschaft).

Skin inspections are done at regular intervals by a doctor competent to recognise the signs and symptoms of substance-related dermatitis, and the results are recorded.

In connection with German national regulations on hazardous substances (GefStoffV) the technical rules on hazardous substances (TRGS 900, Hazardous substances in air) require exposure controls in monitoring limit values at workplaces:

|                 |                                                         |
|-----------------|---------------------------------------------------------|
| Calcium carbide | MAK 2 mg/m <sup>3</sup> (portion of total dust inhaled) |
| Calcium oxide   | MAK 5 mg/m <sup>3</sup> (portion of total dust inhaled) |

### *Emergency Care for Hazardous Materials:*

First aid measures and therapeutic regimes related to poisoning with calcium carbide/calcium oxide/calcium hydroxide were established.

#### **2.3.2 Toxicological end point for assessment of risk following long-term dietary exposure – ADI**

As explained above, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent, no ADI was allocated and was not considered necessary.

#### **2.3.3 Toxicological end point for assessment of risk following acute dietary exposure – ARfD (acute reference dose)**

As explained above, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent, no ARfD was allocated and was not considered necessary.

#### **2.3.4 Toxicological end point for assessment of occupational and bystander risks – AOEL / MOE**

As explained above, in the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal's burrows or tunnels with a simple measurement tool, eliminating operator / bystander exposure. No exposure to workers is foreseen. Thus no AOEL was allocated and was not considered necessary.

### 2.3.5 Drinking water limit

As explained in point 2.3.2 above, no drinking water limit is allocated and is not considered necessary.

### 2.3.6 Impact on human or animal health arising from exposure to calcium carbide or to impurities contained in it

#### Estimation of operator exposure

PRONTOX Wühlmausgas is identical to technical calcium carbide. It is to be sold and applied unformulated, as the technical material.

If the directions for use (see Annex B.6, point B.6.14.1.2) are not noticed PRONTOX Wühlmausgas can cause ill health mainly by skin contact and inhalation of dust.

Dry PRONTOX Wühlmausgas in contact with skin may cause dermatitis.

In contact with moist skin and mucous membranes PRONTOX Wühlmausgas is developing calcium hydroxide, a medium strong alkaline substance.

Small quantities of PRONTOX Wühlmausgas in contact with moist skin give rise to redness, and pain.

Small quantities of PRONTOX Wühlmausgas in contact with eyes lead to redness, pain, and blurred vision.

PRONTOX Wühlmausgas (calcium carbide) is introduced into the target animals underground runs and tunnels by means of a spoon or another aid. The spoon should be designed to both an applicator and a dosage measuring system.

Granules can then be introduced one at a time into the tunnels with a simple, clear, accurate measurement of the dosage, whilst at the same time eliminating operator exposure.

This mode of application effectively and safely prevents inhalation of calcium carbide dust since the user does not come into contact with the product at all. Underground, the evolution of acetylene and phosphine is not abrupt, but depends on the progressive absorption of soil moisture. Since phosphine is heavier than air, it remains within the target animals burrows underground, and because the entrances to the burrow system are closed, the gas ultimately diffuses into the surrounding soil, with no more than trace quantities reaching the surface, well away from the respiration zone of operators or bystanders.

Phosphine has a characteristic garlic-like smell, and this can be detected at 0.02 ppm. This smell threshold concentration is sufficient to dislodge voles and moles.

Acetylene evolved is not absorbed via the skin. Skin contact with PRONTOX Wühlmausgas is effectively prevented by wearing general-purpose protective gloves (plant protection) when applying/handling the product ready for application.

The wind direction must be taken into account to avoid the inhalation of dust of calcium carbide.

#### Measurement of operator exposure

Measurement of operator exposure for the product PRONTOX Wühlmausgas is not considered to be required, since this plant protection product represents a ready-to-use repellent which is placed underground into target animal runs and tunnels.

PRONTOX Wühlmausgas is a granule with a particle size of 4-7 mm. The product shows a very high mechanical stability and a low content of dust (< 0.5 %). Due to this attributes, no relevant exposure of the operator is to be expected. If in contact with moisture acetylene, calcium hydroxide and minor quantities of phosphine will release, no relevant exposure of the operator can be

expected. Phosphine is heavier than air (relative density: 1.18 in relating to air: 1, temperature: 0°C, atmospheric pressure: 1013 hPa), it remains within the target animals' burrows underground, and because the entrance to the burrow system are closed, the gas ultimately diffuses into the surrounding soil, with no more than trace quantities reaching the surface, well away from respiration zone of operators and bystanders. Then phosphine will quickly diluted in air and oxidized to phosphorous acids.

Acetylene evolved is lighter than air (relative density: 0.91 in relating to air: 1, temperature: 0 °C, atmospheric pressure: 1013 hPa) and will quickly diluted in air. Significant quantities, since just 2.5% v/v (lower explosive limit) or greater concentrations in air will not appear. Therefore, acetylene is unlikely to persist in the body.

Calcium hydroxide arose from calcium carbide and from calcium oxide by hydration reacts with carbon dioxide in the soil to form calcium carbonate and bicarbonate. These substances will be absorbed on the soil colloids.

#### Bystander exposure

No exposure for bystanders is expected during the use of PRONTOX Wühlmausgas.

#### Worker exposure

As for operators and bystanders, worker exposure is not expected to occur.

## **2.4 Residues**

Calcium carbide (PRONTOX Wühlmausgas), used as repellent against moles and voles, is introduced into corridors of burrows, where it decomposes in the humidified atmosphere of soils. It is not intended for direct application to growing crops, no residues in plants or in plant food stuffs are to be expected, and it does not enter in the human food chain.

## **2.5 Fate and behaviour in the environment**

### **2.5.1 Definition of the residues relevant to the environment**

Calcium carbide was shown to be very reactive in presence of water, soil moisture or air humidity, with degradation into calcium hydroxide, acetylene and small quantities of phosphine. Calcium hydroxide reacts into ubiquitous bicarbonate and carbonate calcium. Phosphine trapped below surface is quickly adsorbed and degraded in phosphates and acetylene may be used by soil microorganisms affecting indirectly the nitrogen cycle. In water calcium carbide reacts very vigorously into calcium hydroxide, acetylene gas, that dissipates to atmosphere, and minor quantities of phosphine that oxidized to phosphoric acids and phosphates. Since substances released in the environment from reaction of calcium carbide with soil moisture or water are ubiquitous no soil or water residue definition will be proposed.

Calcium carbide will be directly applied, in granules, in tunnels and burrows that should be covered, avoiding releases to air. Two of the degradation products acetylene and phosphine, had volatile properties but both will be trapped underground, his potential to reach surface will be very limited, so no residues in air will be considered.

### **2.5.2 Fate and behaviour in soil**

Calcium carbide technical is a repellent containing 80% w/w calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form as a repellent for voles (*Arvicola terrestris*) and moles (*Talpa europaea*). The useful recommended mode of application is at rate of 10g per tunnel for voles and at rate of 20 g per burrow for moles of technical calcium

carbide. Depending on the infestation level, the application rate should range between 2.5-10kg/ha of technical calcium carbide. The product is intended to be applied once only.

Calcium carbide technical reacts in contact with soil moisture to gas acetylene, small quantities of gas phosphine and solid calcium oxide (calcium hydroxide). Calcium hydroxide reacts with carbon dioxide to calcium bicarbonate and calcium carbonate, other calcium carbide impurities as carbon, aluminium oxide, iron oxide and silicon dioxide are ubiquitous and stable in the soil.

Acetylene released underground inhibits the activity of nitrifying bacteria involved in transformation of ammonium ( $\text{NH}_4^+$ ) in nitrites ( $\text{NO}_2^-$ ) involved in nitrogen cycle. The inhibition of nitrification in soil has been pursued as a strategy to improve recovery of fertilizer nitrogen (N) by crops through lowering losses by leaching of nitrate or denitrification in order to benefit yields and the environment, this may assume particular importance in agricultural soils exposed to successive fertilizations.

Phosphine released underground at small quantities is quickly adsorbed and degraded to phosphates in matter of days. Diffusion through the soil environment is expected to be slow because phosphine is sorbed in seconds when pushed through several types of soil in a nitrogen carrier.

Regarding the intended uses, the calcium carbide properties and the expected degradation process the accumulation in soil of calcium carbide or its degradation products is not predicted.

### 2.5.3 Fate and behaviour in water

Calcium carbide reacts very vigorously in water with spontaneous decomposition into calcium hydroxide, acetylene and small quantities of phosphine. Acetylene gas dissipates to atmosphere and phosphine evolved in minor quantities is oxidized to phosphoric acids and phosphates. Calcium carbide reaction with water shows alkaline reaction.

Regarding the physical and chemical properties of calcium carbide it is not expected that the active substance or any of the decomposition products persist in water. Moreover, regarding the intended use, application underground in tunnels or burrows, it is not expected that the product will reach surface waters.

### 2.5.4 Fate and behaviour in air

The technical calcium carbide is intended to be applied directly below soil surface, at rate of 2.5-10 kg/ha, in tunnels and burrows of agricultural soil, that should be covered after the application.

Calcium carbide technical is not volatile, but in contact with humid air reacts with spontaneous decomposition into calcium hydroxide, to acetylene gas and phosphine gas. Phosphine in the atmosphere is rapidly degraded with half-life in air of approximately five hours, by photoreaction with hydroxyl radicals. The dark half-life is approximately 28 hours. The expected reaction products of phosphine in air are oxyacids of phosphorous and inorganic phosphate which are non-volatile. Acetylene is highly flammable gas and can form explosive mixtures with air.

Regarding the intended uses of product, granules applied directly under soil surface, no releases of the product to air can occur. Considering that the volatile degradation products, acetylene and phosphine, will be trapped in soil, releases of those substances to air should be considered negligible. So, air will not be exposed to calcium carbide or to the degradation products.

## 2.6 Effects on non-target species

### 2.6.1 Effects on terrestrial vertebrates

#### 2.6.1.1 Birds

PRONTOX Wuhlmausgas or calcium carbide technical is a repellent containing 80% w/w calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form for the control of voles (*Arvicola terrestris*) and moles (*Talpa europaea*). The useful recommended mode of application is at rate of 10g PRONTOX Wuhlmausgas/ tunnel (voles) and at rate of 20g PRONTOX Wuhlmausgas/burrow (moles). The application rate ranges between 2.5-10kg product/ha. The product is intended to be applied once only, after application burrows and tunnels should be covered. Between two or four days after treatment inspection of the rodent holes or burrows must be done.

Calcium carbide placed in tunnels and burrows in contact with soil moisture breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of gas phosphine. Phosphine is known as a powerful respiratory poison, since is highly toxic by inhalation at low concentrations, used as rodenticide and insecticide, moreover phosphine is the substance responsible for the repellent action by its characteristic garlic-like smell in technical calcium carbide. For that reason the emissions of phosphine underground can not be ignored and risks to birds should be addressed.

Regarding the intended use, birds would not be directly exposed to this product or to degradation products. However, birds can be indirectly exposed to the product or degradation products by ingestion of contaminated food, as soil insects, earthworms and plants, so herbivorous birds, insectivorous birds and earthworm eating birds can be exposed to the degradation products, in particular to phosphine.

After an assessment based on the limited data and on unrealistic worst case scenario it was possible to consider that birds can be exposed to calcium phosphide at residual levels. The values estimated for calcium phosphide daily food intake for an insectivorous bird or earthworm eating birds were considered residual. In addition, the substance that might cause adverse effects to soil organisms is phosphine gas, that when released in small amounts is rapidly adsorbed and degraded to phosphates, so soil organisms will be exposed to concentrations much lower than the considered in the estimate. Although there is no data or studies to support the conclusions, considering the behaviour of calcium carbide in soil and the previous considerations, risk to birds can be considered negligible.

#### 2.6.1.2 Vertebrates other than birds

PRONTOX Wuhlmausgas, in granular form should be placed inside tunnels and burrows, that should be covered in the end of application. In contact with soil moisture breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of gas phosphine. Phosphine is classified as toxic based on acute effects via the inhalation route of exposure, acting as a powerful poison.

Risk to terrestrial vertebrates should be addressed. Mammals can be exposed directly to the product, in particular other non-target mammals that below soil surface (eg. rabbits). Considering the inhalation acute and short term toxicity values estimated for rats when exposed to phosphine and the estimated values of calcium phosphide released underground, that represent an overestimated value of the concentration of phosphine it is possible to conclude that the risk to mammals by direct exposure can be considered very low.

After an assessment based on the limited data and on unrealistic worst case scenario it was possible

to consider that mammals can be exposed to calcium phosphide at residual levels by food intake. The values estimated for of calcium phosphide daily food intake for an insectivorous mammal or earthworm eating mammal were considered residual. In addition, the substance that might cause adverse effects to soil organisms is phosphine gas, that when released in small amounts is rapidly adsorbed and degraded to phosphates, so soil organisms will be exposed to concentrations much lower than the considered in the estimative. Although there is no data or studies to support the conclusions, considering the behaviour of calcium carbide in soil and the previous considerations, risk to mammals can be considered negligible.

### 2.6.2 Effects on aquatic species

The studies conducted with aquatic organisms indicate that calcium carbide technical is toxic to aquatic organisms. However should be considered that calcium carbide reacts vigorously in water into calcium hydroxide, acetylene and small amounts of phosphine. The alkaline reaction increase water pH, immediately after calcium carbide application, in particular at higher concentrations, can have some influence on test results with aquatic organisms. The degradation product calcium hydroxide might be responsible for the toxic effects. The other degradation products should not affect the toxicity effects of calcium carbide technical in water since acetylene is an very volatile substance not classified to the environment, and although the calcium phosphide is classified as very toxic to aquatic organisms (classified on the basis of the phosphine, very toxic to aquatic organisms but not stable in water) it is present at residual levels in the technical product, moreover at low level phosphine may be oxidized to phosphoric acids and phosphates. So the influence of acetylene and phosphine for aquatic toxicity might be considered negligible.

The calcium carbide technical, as well as the product PRONTOX Wuhlmausgas, since product and technical substance are the same, should be classified as Toxic to aquatic organisms. Regarding the intended use of the product the exposure of surface water should be negligible; the aquatic environment should not be at risk.

### 2.6.3 Effects on bees and other arthropod species

Regarding that calcium carbide is intended to use only arthropods species that live underground may be exposed to calcium carbide degradation product phosphine. Phosphine is used not only as rodenticide abut also as insecticide, acting in the respiratory chain. The effects depend on insect respiratory rhythm or for stages of development. Adult insects withstanding concentrations of 1000-2000 ppm, whereas a susceptible insect dies in a few hours at 30 ppm (Ducom, nd<sup>1</sup>). Arthropods and bees, which live above soil surface, would not be exposed to this products or degradation products.

Regarding the low content of calcium phosphide in the technical product (0.025-0.05 w/w), at the maximum application rate of 10 Kg product/ha, the maximum concentration of calcium phosphide in soil is 0.0066mg/kg. Regarding that the substance that might cause adverse effects to soil organisms is phosphine gas, and that the release of phosphine from calcium phosphide is gradual, and that underground this substance is adsorbed and degraded to phosphates. The concentration that soil insects can be exposed should be much lower than the estimated, so the risk to non-target soil arthropods can be considered very low. Although there is no data or studies to support the conclusions, considering the behaviour of calcium carbide in soil and the previous considerations, risk to bees and other arthropods can be considered low.

<sup>1</sup> Ducom, Patrick. The issue of Phosphine insecticide efficacy. Laboratoire National Denrées Stockées. Bordeaux.

#### 2.6.4 Effects on earthworms and other soil macro-organisms

Calcium carbide placed in tunnels and burrows in contact with soil moisture breaks down rapidly to produce the gas acetylene, solid calcium hydroxide and minor quantities of gas phosphine, very toxic substance. Phosphine is produced by calcium phosphide, one impurity of technical calcium carbide.

Regarding the intended use of this product, phosphine will volatilise into the soil holes and burrows, i.e., phosphine could be trapped in soil since the holes should be covered after application of the product. Earthworms can be exposed to calcium carbide degradation product, phosphine a very toxic substance. Regarding that phosphine released underground at low level can be quickly adsorbed and degraded to phosphates the exposure of earthworms to this substance should be very low. Although there is no data or studies to support the conclusions, considering the behaviour of calcium carbide in soil and the previous considerations, risk earthworms can be considered low.

#### 2.6.5 Effects on soil micro-organisms

Regarding the intended use of this product micro-organisms living underground can be exposed to calcium carbide degradation products, including phosphine, a very toxic substance. However, as mentioned before the level of phosphine released underground can be considered residual and at low concentrations soil can quickly adsorbed and degraded. Acetylene underground can inhibit the activity of nitrifying bacteria. No other effects to micro-organisms were registered for the technical product. Although the absence of information to support a risk assessment risk to soil micro-organisms can be considered low.

#### 2.6.6 Effects on other non-target organisms (flora and fauna)

The product is intended to be used in agriculture soils, so plants (crops/ornamental) can be exposed to the product or degradation products, by roots. It is not foreseeable that calcium carbide affects plants. Moreover, the calcium carbide degradation products in soil, as calcium ions, bicarbonate and phosphates, are taken up and metabolised by plants as trace nutrients, so plants can benefit indirectly with the application of calcium carbide in soil.

#### 2.6.7 Effects on biological methods of sewage treatment

No releases should occur to sewage plant treatment regarding the intended uses of the product, so no biological effects are expected to occur to sewage organisms.

### 2.7 Efficacy

#### 2.7.1 Effectiveness against target organisms, or with respect to the effect achieved

PRONTOX Wühlmausgas (Calcium carbide) is reported to be a repellent containing 80 % w/w carbide and minor quantities (0.025 - 0.05 % w/w) of Calcium phosphide. It is applied in granular form for the control of voles (*Arvicola terrestris*) and moles (*Talpa europaea*). It is sold unformulated as the technical active ingredient, and thus the composition of the formulation and the technical active ingredient are the same. The recommended mode of application is at a rate of 10g PRONTOX Wühlmausgas/tunnel (*Arvicola terrestris*) and at a rate of 20g PRONTOX Wühlmausgas/ burrow (*Talpa europaea*). Depending on the context of infestation, this is considered to correspond to a maximum field application rate of 2.5-5kg/ha. The product is intended to be applied once only. If upon inspection of the rodent holes or moles' hills 2-4 days after application, no vole and mole activity is apparent, then further applications are not necessary. If required PRONTOX Wühlmausgas may be used at any time of year and the duration of protection is principally unrestricted. A proposal of necessary waiting periods or other precautions

to avoid effects on succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required, since uptake in plants is not to be expected. Limitations on choice of succeeding crops for the product PRONTOX Wühlmausgas is not considered to be required.

### 2.7.1.1 Mode of action

Calcium carbide is placed in tunnels and burrows of target pests in non-crop situations, away from buildings. In contact with moisture in the soil Calcium carbide breaks down rapidly to produce the gas Acetylene, solid Calcium hydroxide and minor quantities of the gas Phosphine. The repellent action of technical Calcium carbide on harmful organisms (voles and moles) is based on the garlic-like odour of Phosphine.

### 2.7.1.2 Fields of use

The existing and intended use of Calcium carbide is the protection of agricultural crops, vegetable, fruit and ornamental growing and grassland against damage by voles (*Arvicola terrestris*) and moles (*Talpa europaea*), respectively.

### 2.7.1.3 Effectiveness against target-organisms

The repellent action of the active substance technical Calcium carbide (PRONTOX Wühlmausgas) have been established for more than 30 years. Its successful use as an active ingredient against rodentia and insectivora such as voles and moles. With reference to the effective dose of Calcium carbide for voles (*Arvicola terrestris*) and moles (*Talpa europaea*) 10g, or 20g Calcium carbide (80% w/w a.i.), respectively, would be sufficient to dislodge the target animals. Based on these findings and according to the experience in more than 30 years, the following label claims are justified:

**Table 2.7 – 1 - Proposed label claims for the efficacy of PRONTOX Wühlmausgas**

| Susceptible pests          |              |                 |
|----------------------------|--------------|-----------------|
| Scientific name            | English name | German name     |
| <i>Arvicola terrestris</i> | Common vole  | Scher-/Wühlmaus |
| <i>Talpa Europaea</i>      | common mole  | Maulwurf        |

### 2.7.2 Possible occurrence of the development of resistance

The applicant is not aware of any occurrence of resistance against PRONTOX Wühlmausgas (Calcium carbide) in relevant susceptible pests. This lack of development of resistance of voles and moles to the product is assumed to be related to the inorganic nature of the active ingredient.

### 2.7.3 Effects on the quality of plants or plant products

Any potential effects on the yield of treated plants or plant products in terms of quantity and/or quality from the GAP use of PRONTOX Wühlmausgas are not to be expected, for the following reasons: PRONTOX Wühlmausgas is not intended for direct application to growing crops, and thus no residues in plants or in plant food stuffs are expected. Unlike conventional crop protection products, which must be applied over relatively large crop areas, Calcium carbide repellents like PRONTOX Wühlmausgas are predominantly applied to discrete sites in the form of granule directly into the runs/ holes of voles and moles. Due to the GAP use and the rapid decomposition of the

active ingredient in the soil, technical Calcium carbide is degraded to Calcium hydroxide, Acetylene and minor quantities of Phosphine and will not be washed out, and any relevant uptake by plants is excluded. Whereas the first is a normal constituent of soil, Acetylene and Phosphine are gases subject either to rapid atmospheric degradation upon volatilisation, or it may be re-adsorbed onto soil and subsequently be degraded to phosphate. Therefore, no soil accumulation is expected to occur. In the soil, Calcium ions, bicarbonate and phosphate are taken up and metabolised by plants as trace nutrients.

#### **2.7.4 Effects on transformation processes**

Such effects are not to be expected for reasons given above.

#### **2.7.5 Effects on the yield of treated plants or plant products**

Such effects are not to be expected for reasons given above.

#### **2.7.6 Phytotoxicity to target plants or target plant products**

Tests on phytotoxicity to target plants (including different cultivars), or to target plant products following the use of the product PRONTOX Wühlmausgas were not conducted. Such tests are not considered to be required.

#### **2.7.7 Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation**

No impact on succeeding crops is to be expected, and no studies were conducted, since there is no danger that significant residues of the active substance and his metabolites remain unchanged in soil or in plant materials up to sowing or planting time of succeeding crops and which could lead to any residues at harvest. See 2.6.6.

Impacts on seed viability are not to be expected, and because of lack of exposure of any plants or adjacent crops.

#### **2.7.8 Tank mixing recommendations**

Not applicable. Product ready to use.

## **CALCIUM CARBIDE**

### **LEVEL 2**

Appendix 1: Standard terms and abbreviations

## Appendix 1 Standard terms and abbreviations

### Part 1 Technical terms

|        |                                                                                                 |
|--------|-------------------------------------------------------------------------------------------------|
| A      | ampere                                                                                          |
| Ach    | acetylcholine                                                                                   |
| ACH    | acetylcholinesterase                                                                            |
| ADI    | acceptable daily intake                                                                         |
| ADP    | adenosine diphosphate                                                                           |
| AE     | acid equivalent                                                                                 |
| AFID   | alkali flame-ionization detector or detection                                                   |
| A/G    | albumin/globulin ratio                                                                          |
| ai     | active ingredient                                                                               |
| ALD50  | approximate median lethal dose, 50%                                                             |
| ALT    | alanine aminotransferase (SGPT)                                                                 |
| AOEL   | acceptable operator exposure level                                                              |
| AMD    | automatic multiple development                                                                  |
| ANOVA  | analysis of variance                                                                            |
| AP     | alkaline phosphatase                                                                            |
| approx | approximate                                                                                     |
| ARC    | anticipated residue contribution                                                                |
| ARfD   | acute reference dose                                                                            |
| as     | active substance                                                                                |
| AST    | aspartate aminotransferase (SGOT)                                                               |
| ASV    | air saturation value                                                                            |
| ATP    | adenosine triphosphate                                                                          |
| BCF    | bioconcentration factor                                                                         |
| bfa    | body fluid assay                                                                                |
| BOD    | biological oxygen demand                                                                        |
| bp     | boiling point                                                                                   |
| BSAF   | biota-sediment accumulation factor                                                              |
| BSE    | bovine spongiform encephalopathy                                                                |
| BSP    | bromosulphthalein                                                                               |
| Bt     | bacillus thuringiensis                                                                          |
| Bti    | bacillus thuringiensis israelensis                                                              |
| Btk    | bacillus thuringiensis kurstaki                                                                 |
| Btt    | bacillus thuringiensis tenebrionis                                                              |
| BUN    | blood urea nitrogen                                                                             |
| bw     | body weight                                                                                     |
| c      | centi- ( $\times 10^{-2}$ )                                                                     |
| °C     | degree Celsius (centigrade)                                                                     |
| CA     | controlled atmosphere                                                                           |
| CAD    | computer aided design                                                                           |
| CADDY  | computer aided dossier and data supply (an electronic dossier interchange and archiving format) |
| cd     | candela                                                                                         |
| CDA    | controlled drop(let) application                                                                |
| cDNA   | complementary DNA                                                                               |
| CEC    | cation exchange capacity                                                                        |
| cf     | confer, compare to                                                                              |
| CFU    | colony forming units                                                                            |
| ChE    | cholinesterase                                                                                  |
| CI     | confidence interval                                                                             |
| CL     | confidence limits                                                                               |
| cm     | centimetre                                                                                      |
| CNS    | central nervous system                                                                          |
| COD    | chemical oxygen demand                                                                          |
| CPK    | creatinine phosphatase                                                                          |
| cv     | coefficient of variation                                                                        |
| CXL    | Codex Maximum Residue Limit (Codex MRL)                                                         |

|        |                                                                       |
|--------|-----------------------------------------------------------------------|
| d      | day                                                                   |
| DES    | diethylstilboestrol                                                   |
| DFR    | dislodgeable foliar residue                                           |
| DMSO   | dimethylsulphoxide                                                    |
| DNA    | deoxyribonucleic Acid                                                 |
| dna    | designated national authority                                         |
| DO     | dissolved oxygen                                                      |
| DOC    | dissolved organic carbon                                              |
| dpi    | days pot inoculation                                                  |
| DRES   | dietary risk evaluation system                                        |
| DT50   | period required for 50 percent dissipation (define method estimation) |
| DT90   | period required for 90 percent dissipation (define method estimation) |
| dw     | dry weight                                                            |
| DWQG   | drinking water quality guidelines                                     |
| $\xi$  | decadic molar extinction coefficient                                  |
| EC50   | median effective concentration                                        |
| ECD    | electron capture detector                                             |
| ECU    | European currency unit                                                |
| ED50   | median effective dose                                                 |
| EDI    | estimated daily intake                                                |
| ELISA  | enzyme linked immunosorbent assay                                     |
| e-mail | electronic mail                                                       |
| EMDI   | estimated maximum daily intake                                        |
| EPMA   | electron probe micro analysis                                         |
| ERC    | environmentally relevant concentration                                |
| ERL    | extraneous residue limit                                              |
| F      | field                                                                 |
| F0     | parental generation                                                   |
| F1     | filial generation, first                                              |
| F2     | filial generation, second                                             |
| FIA    | fluorescence immuno assay                                             |
| FID    | flame ionization detector                                             |
| FOB    | functional observation battery                                        |
| fp     | freezing point                                                        |
| FPD    | flame photometric detector                                            |
| FPLC   | fast protein liquid chromatography                                    |
| g      | gram                                                                  |
| G      | glasshouse                                                            |
| GAP    | good agricultural practice                                            |
| GC     | gas chromatography                                                    |
| GC-EC  | gas chromatography with electron capture detector                     |
| GC-FID | gas chromatography with flame ionization detector                     |
| GC-MS  | gas chromatography-mass spectrometry                                  |
| GEP    | good experimental practice                                            |
| GFP    | good field practice                                                   |
| GGT    | gamma glutamyl transferase                                            |
| GI     | gastro-intestinal                                                     |
| GIT    | gastro.intestinal tract                                               |
| GL     | guideline level                                                       |
| GLC    | gas liquid chromatography                                             |
| GLP    | good laboratory practice                                              |
| GM     | geometric mean                                                        |
| GMO    | genetically modified organism                                         |
| GMM    | genetically modified micro-organism                                   |
| GPC    | gel-permeation chromatography                                         |
| GPPP   | good plant protection practice                                        |
| GPS    | global positioning system                                             |
| GSH    | glutathion                                                            |

|          |                                                                                                    |
|----------|----------------------------------------------------------------------------------------------------|
| GV       | granulosevirus                                                                                     |
| h        | hour(s)                                                                                            |
| H        | Henry's Law constant (calculated as a unitless value) (see also K)                                 |
| ha       | hectare                                                                                            |
| Hb       | haemoglobin                                                                                        |
| HCG      | human chorionic gonadotropin                                                                       |
| Hct      | haematocrit                                                                                        |
| HDT      | highest dose tested                                                                                |
| hL       | hectolitre                                                                                         |
| HEED     | high energy electron diffraction                                                                   |
| HID      | helium ionization detector                                                                         |
| HPAEC    | high performance anion exchange chromatography                                                     |
| HPLC     | high pressure liquid chromatography or high performance liquid chromatography                      |
| HPLC-MS  | high pressure liquid chromatography – mass spectrometry                                            |
| HPPLC    | high pressure planar liquid chromatography                                                         |
| HPTLC    | high performance thin layer chromatography                                                         |
| HS       | Shannon-Weaver index                                                                               |
| Ht       | haematocrit                                                                                        |
| I        | indoor                                                                                             |
| I50      | inhibitory dose, 50%                                                                               |
| IC50     | median immobilization concentration or median inhibitory concentration <sup>1</sup>                |
| ICM      | integrated crop management                                                                         |
| ID       | ionization detector                                                                                |
| IEDI     | international estimated daily intake                                                               |
| IGR      | insect growth regulator                                                                            |
| im       | intramuscular                                                                                      |
| inh      | inhalation                                                                                         |
| ip       | intraperitoneal                                                                                    |
| IPM      | integrated pest management                                                                         |
| IR       | infrared                                                                                           |
| ISBN     | international standard book number                                                                 |
| ISSN     | international standard serial number                                                               |
| iv       | intravenous                                                                                        |
| IVF      | in vitro fertilisation                                                                             |
| k        | kilo                                                                                               |
| K        | Kelvin or Henry's Law constant (in atmospheres per cubic meter per mole) (see also H) <sup>1</sup> |
| Kads     | adsorption constant                                                                                |
| Kdes     | apparent desorption coefficient                                                                    |
| Koc      | organic carbon adsorption coefficient                                                              |
| Kom      | organic matter adsorption coefficient                                                              |
| kg       | kilogram                                                                                           |
| L        | litre                                                                                              |
| LAN      | local area network                                                                                 |
| LASER    | light amplification by stimulated emission of radiation                                            |
| LBC      | loosely bound capacity                                                                             |
| LC       | liquid chromatography                                                                              |
| LC-MS    | liquid chromatography – mass spectrometry                                                          |
| LC50     | lethal concentration, median                                                                       |
| LCA      | life cycle analysis                                                                                |
| LCLO     | lethal concentration low                                                                           |
| LC-MS-MS | liquid chromatography with tandem mass spectrometry                                                |
| LD50     | lethal dose, median; dosis letalis media                                                           |
| EDLO     | lethal dose low                                                                                    |
| LDH      | lactate dehydrogenase                                                                              |
| LOAEC    | lowest observable adverse effect concentration                                                     |

<sup>1</sup> The first time the abbreviation is used in a document, it should be defined (using a footnote to do so)

|       |                                                                                 |
|-------|---------------------------------------------------------------------------------|
| LOAEL | lowest observable adverse effect level                                          |
| LOD   | limit of detection                                                              |
| LOEC  | lowest observable effect concentration                                          |
| LOEL  | lowest observable effect level                                                  |
| LOQ   | limit of quantification (determination)                                         |
| LPLC  | low pressure liquid chromatography                                              |
| LSC   | liquid scintillation counting or counter                                        |
| LSD   | least squared denominator multiple range test                                   |
| LSS   | liquid scintillation spectrometry                                               |
| LT    | lethal threshold                                                                |
| m     | meter                                                                           |
| M     | molar                                                                           |
| µm    | micrometer (micron)                                                             |
| MC    | moisture content                                                                |
| MCH   | mean corpuscular haemoglobin                                                    |
| MCHC  | mean corpuscular haemoglobin concentration                                      |
| MCV   | mean corpuscular volume                                                         |
| MDL   | method detection limit                                                          |
| MFO   | mixed function oxidase                                                          |
| µg    | microgram                                                                       |
| mg    | milligram                                                                       |
| MHC   | moisture holding capacity                                                       |
| min   | minute(s)                                                                       |
| mL    | millilitre                                                                      |
| MLT   | median lethal time                                                              |
| MLD   | minimum lethal dose                                                             |
| mm    | millimetre                                                                      |
| mo    | month(s)                                                                        |
| mol   | Mole(s)                                                                         |
| MOS   | margin of safety                                                                |
| mp    | melting point                                                                   |
| MRE   | maximum residue expected                                                        |
| MRL   | maximum residue level or limit                                                  |
| mRNA  | messenger ribonucleic acid                                                      |
| MS    | mass spectrometry                                                               |
| MSDS  | material safety data sheet                                                      |
| MTD   | maximum tolerated dose                                                          |
| n     | normal (defining isomeric configuration) or number of observations <sup>1</sup> |
| NAEL  | no adverse effect level                                                         |
| nd    | not detected                                                                    |
| NEDI  | national estimated daily intake                                                 |
| NEL   | no effect level                                                                 |
| NERL  | no effect residue level                                                         |
| ng    | nanogram                                                                        |
| nm    | nanometer                                                                       |
| NMR   | nuclear magnetic resonance                                                      |
| no    | number                                                                          |
| NOAEC | no observed adverse effect concentration                                        |
| NOAEL | no observed adverse effect level                                                |
| NOEC  | no observed effect concentration                                                |
| NOED  | no observed effect dose                                                         |
| NOEL  | no observed effect level                                                        |
| NOIS  | notice of intent to suspend                                                     |
| NPD   | nitrogen-phosphorus detector or detection                                       |
| NPV   | nuclear polyhedrosis virus                                                      |
| NR    | not reported                                                                    |
| NTE   | neurotoxic target esterase                                                      |

<sup>1</sup> The first time the abbreviation is used in a document, it should be defined (using a footnote to do so)

|                |                                                                  |
|----------------|------------------------------------------------------------------|
| OC             | organic carbon content                                           |
| OCR            | optical character recognition                                    |
| ODP            | ozone-depleting potential                                        |
| ODS            | ozone-depleting substances                                       |
| OM             | organic matter content                                           |
| op             | organophosphorus pesticide                                       |
| Pa             | Pascal                                                           |
| PAD            | pulsed amperometric detection                                    |
| 2-PAM          | 2-pralidixime                                                    |
| pc             | paper chromatography                                             |
| PC             | personal computer                                                |
| PCV            | haematocrit (packed corpuscular volume)                          |
| PEC            | predicted environmental concentration                            |
| PECA           | predicted environmental concentration in air                     |
| PECS           | predicted environmental concentration in soil                    |
| PECSW          | predicted environmental concentration in surface water           |
| PECGW          | predicted environmental concentration in ground water            |
| PED            | plasma-emissions-detector                                        |
| pH             | pH-value                                                         |
| PHED           | pesticide handler's exposure data                                |
| PHI            | pre-harvest interval                                             |
| PIC            | prior informed consent                                           |
| pic            | phage inhibitory capacity                                        |
| PIXE           | proton induced X-ray emission                                    |
| pKa            | negative logarithm (to the base 10) of the dissociation constant |
| PNEC           | predicted no effect concentration                                |
| po             | by mouth                                                         |
| POW            | partition coefficient between n-octanol and water                |
| POP            | persistent organic pollutants                                    |
| ppb            | parts per billion ( $10^{-9}$ )                                  |
| PPE            | personal protective equipment                                    |
| ppm            | parts per million ( $10^{-6}$ )                                  |
| ppp            | plant protection product                                         |
| ppq            | parts per quadrillion ( $10^{-24}$ )                             |
| ppt            | parts per trillion ( $10^{-12}$ )                                |
| PSP            | phenolsulfophthalein                                             |
| PrT            | prothrombin time                                                 |
| PRL            | practical residue limit                                          |
| PT             | prothrombin time                                                 |
| PTDI           | provisional tolerable daily intake                               |
| PTT            | partial thromboplastin time                                      |
| QSAR           | quantitative structure-activity relationship                     |
| r              | correlation coefficient                                          |
| r <sup>2</sup> | coefficient of determination                                     |
| RBC            | red blood cell                                                   |
| REI            | restricted entry interval                                        |
| Rf             | retardation factor                                               |
| RfD            | reference dose                                                   |
| RH             | relative humidity                                                |
| RL50           | median residual lifetime                                         |
| RNA            | ribonucleic acid                                                 |
| RP             | reversed phase                                                   |
| rpm            | rotations per minute                                             |
| rRNA           | ribosomal ribonucleic acid                                       |
| RRT            | relative retention time                                          |
| RSD            | relative standard deviation                                      |

s

second

|          |                                                      |
|----------|------------------------------------------------------|
| SAC      | strong adsorption capacity                           |
| SAP      | serum alkaline phosphatase                           |
| SAR      | structure/activity relationship                      |
| SBLC     | shallow bed liquid chromatography                    |
| sc       | subcutaneous                                         |
| sce      | sister chromatid exchange                            |
| SD       | standard deviation                                   |
| se       | standard error                                       |
| SEM      | standard error of the mean                           |
| SEP      | standard evaluation procedure                        |
| SF       | safety factor                                        |
| SFC      | supercritical fluid chromatography                   |
| SFE      | supercritical fluid extraction                       |
| SIMS     | secondary ion mass spectroscopy                      |
| SOP      | standard operating procedures                        |
| sp       | species (only after a generic name)                  |
| SPE      | solid phase extraction                               |
| SPF      | specific pathogen free                               |
| spp      | subspecies                                           |
| sq       | square                                               |
| SSD      | sulphur specific detector                            |
| SSMS     | spark source mass spectrometry                       |
| STEL     | short term exposure limit                            |
| STMR     | supervised trials median residue                     |
| t        | tonne (metric ton)                                   |
| t1/2     | half-life (define method of estimation)              |
| T3       | tri-iodothyroxine                                    |
| T4       | thyroxine                                            |
| TADI     | temporary acceptable daily intake                    |
| TBC      | tightly bound capacity                               |
| TCD      | thermal conductivity detector                        |
| TCLO     | toxic concentration, low                             |
| TID      | themionic detector, alkali flame detector            |
| TDLO     | toxic dose low                                       |
| TDR      | time domain reflectometry                            |
| TER      | toxicity exposure ration                             |
| TERI     | toxicity exposure ration for initial exposure        |
| TERST    | toxicity exposure ration following repeated exposure |
| TERLT    | toxicity exposure ration following chronic exposure  |
| tert     | tertiary (in a chemical name)                        |
| TEP      | typical end-use product                              |
| TGGE     | temperature gradient gel electrophoresis             |
| TIFF     | tag image file format                                |
| TLC      | thin layer chromatography                            |
| TIm      | median tolerance limit                               |
| TLV      | threshold limit value                                |
| TMDI     | theoretical maximum daily intake                     |
| TMRC     | theoretical maximum residue contribution             |
| TMRL     | theoretical maximum residue limit                    |
| TOC      | total organic carbon                                 |
| Tremcard | Transport emergency card                             |
| tRNA     | transfer ribonucleic acid                            |
| TSH      | thyroid stimulating hormone (thyrotropin)            |
| TWA      | time weighted average                                |
| UDS      | unscheduled DNA synthesis                            |
| UF       | uncertainty factor (safety factor)                   |
| ULV      | ultra low volume                                     |
| UV       | ultraviolet                                          |
| v/v      | volume ratio (volume per volume)                     |

|      |                             |
|------|-----------------------------|
| WBC  | white blood cell            |
| wk   | week                        |
| wt   | weight                      |
| w/v  | weight per volume           |
| ww   | wet weight                  |
| w/w  | weight per weight           |
| XRFA | X-ray fluorescence analysis |
| yr   | year                        |
| <    | less than                   |
| ≤    | less than or equal to       |
| >    | greater than                |
| ≥    | greater than or equal to    |

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## Part 2 Organisations and publications

|              |                                                                                                                      |
|--------------|----------------------------------------------------------------------------------------------------------------------|
| ACPA         | American Crop Protection Association                                                                                 |
| ASTM         | American Society for Testing and Materials                                                                           |
| BA           | Biological Abstracts (Philadelphia)                                                                                  |
| BART         | Beneficial Arthropod Registration Testing Group                                                                      |
| CA           | Chemical Abstracts                                                                                                   |
| CAB          | Centre for Agriculture and Biosciences International                                                                 |
| CAC          | Codex Alimentarius Commission                                                                                        |
| CAS          | Chemical Abstracts Service                                                                                           |
| CCFAC        | Codex Committee on Food Additives and Contaminants                                                                   |
| CCGP         | Codex Committee on General Principles                                                                                |
| CCPR         | Codex Committee on Pesticide Residues                                                                                |
| CCRVDF       | Codex Committee on Residues of Veterinary Drugs in Food                                                              |
| CE           | Council of Europe                                                                                                    |
| CIPAC        | Collaborative International Pesticides Analytical Council Ltd                                                        |
| COREPER      | Comite des Representants Permanents                                                                                  |
| EC           | European Commission                                                                                                  |
| ECB          | European Chemical Bureau                                                                                             |
| ECCA         | European Crop Care Association                                                                                       |
| ECDIN        | Environmental Chemicals Data and Information Network of the European Communities                                     |
| ECDIS        | European Environmental Chemicals Data and Information System                                                         |
| ECE          | Economic Commission for Europe                                                                                       |
| ECETOC       | European Chemical Industry Ecology and Toxicology Centre                                                             |
| ECLO         | Emergency Centre for Locust Operations                                                                               |
| ECMWF        | European Centre for Medium Range Weather Forecasting                                                                 |
| ECPA         | European Crop Protection Association                                                                                 |
| EDEXIM       | European Database on Export and Import of Dangerous Chemicals                                                        |
| EFSA         | European Food Safety Authority                                                                                       |
| EHC (number) | Environmental Health Criteria (number)                                                                               |
| EINECS       | European Inventory of Existing Commercial Chemical Substances                                                        |
| ELINCS       | European List of New Chemical Substances                                                                             |
| EMIC         | Environmental Mutagens Information Centre                                                                            |
| EPA          | Environmental Protection Agency                                                                                      |
| EPO          | European Patent Office                                                                                               |
| EPPO         | European and Mediterranean Plant Protection Organization                                                             |
| ESCORT       | European Standard Characteristics of Beneficials Regulatory Testing                                                  |
| EU           | European Union                                                                                                       |
| EUPHIDS      | European Pesticide Hazard Information and Decision Support System                                                    |
| EUROPOEM     | European Predictive Operator Exposure Model                                                                          |
| FAO          | Food and Agriculture Organization of the UN                                                                          |
| FOCUS        | Forum for the Co-ordination of Pesticide Fate Models and their Use                                                   |
| FRAC         | Fungicide Resistance Action Committee                                                                                |
| GATT         | General Agreement on Tariffs and Trade                                                                               |
| GAW          | Global Atmosphere Watch                                                                                              |
| GIFAP        | Groupeement International des Associations Nationales de Fabricants de Produits Agrochimiques<br>(now known as GCPF) |
| GCOS         | Global Climate Observing System                                                                                      |
| GCPF         | Global Crop Protection Federation (formerly known as GIFAP)                                                          |
| GEDD         | Global Environmental Data Directory                                                                                  |
| GEMS         | Global Environmental Monitoring System                                                                               |
| GIEWS        | Global Information and Early Warning System for Food and Agriculture                                                 |
| GRIN         | Germplasm Resources Information Network                                                                              |
| HRAC         | Herbicide Resistance Action Committee                                                                                |

|         |                                                                                                                                                                                  |
|---------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| IARC    | International Agency for Research on Cancer                                                                                                                                      |
| IATS    | International Academy of Toxicological Science                                                                                                                                   |
| IBT     | Industrial Bio-Test Laboratories                                                                                                                                                 |
| ICBB    | International Commission of Bee Botany                                                                                                                                           |
| ICBP    | International Council for Bird Preservation                                                                                                                                      |
| ICES    | International Council for the Exploration of the Seas                                                                                                                            |
| ICPBR   | International Commission for Plant-Bee Relationships                                                                                                                             |
| ILO     | International Labour Organization                                                                                                                                                |
| IMO     | International Maritime Organisation                                                                                                                                              |
| IOBC    | International Organization for Biological Control of Noxious Animals and Plants                                                                                                  |
| IPCS    | International Programme on Chemical Safety                                                                                                                                       |
| IRAC    | Insecticide Resistance Action Committee                                                                                                                                          |
| IRC     | International Rice Commission                                                                                                                                                    |
| ISCO    | International Soil Conservation Organization                                                                                                                                     |
| ISO     | International Organization for Standardization                                                                                                                                   |
| IUPAC   | International Union of Pure and Applied Chemistry                                                                                                                                |
| JECFA   | FAO/WHO Joint Expert Committee on Food Additives                                                                                                                                 |
| JFCNT   | Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme                                                                                                            |
| JMP     | Joint Meeting on Pesticides (WHO/FAO)                                                                                                                                            |
| JMPR    | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| NATO    | North Atlantic Treaty Organisation                                                                                                                                               |
| NAFTA   | North American Free Trade Agreement                                                                                                                                              |
| NCI     | National Cancer Institute (USA)                                                                                                                                                  |
| NCTR    | National Centre for Toxicological Research (USA)                                                                                                                                 |
| NGO     | non-governmental organization                                                                                                                                                    |
| NTP     | National Toxicology Programme (USA)                                                                                                                                              |
| OECD    | Organization for Economic Co-operation and Development                                                                                                                           |
| OLIS    | On-line Information Service of OECD                                                                                                                                              |
| PAN     | Pesticide Action Network                                                                                                                                                         |
| PRAPeR  | Pesticide Risk Assessment Peer Review                                                                                                                                            |
| RNN     | Re-registration Notification Network                                                                                                                                             |
| RTECS   | Registry of Toxic Effects of Chemical Substances (USA)                                                                                                                           |
| SCPH    | Standing Committee on Plant Health                                                                                                                                               |
| SETAC   | Society of Environmental Toxicology and Chemistry                                                                                                                                |
| SI      | Système International d'Unités                                                                                                                                                   |
| SITC    | Standard International Trade Classification                                                                                                                                      |
| TOXLINE | Toxicology Information On-line                                                                                                                                                   |
| UN      | United Nations                                                                                                                                                                   |
| UNEP    | United Nations Environment Programme                                                                                                                                             |
| WCDP    | World Climate Data Programme                                                                                                                                                     |
| WCP     | World Climate Programme                                                                                                                                                          |
| WCRP    | World Climate Research Programme                                                                                                                                                 |
| WFP     | World Food Programme                                                                                                                                                             |
| WHO     | World Health Organization                                                                                                                                                        |
| WTO     | World Trade Organization                                                                                                                                                         |
| WWF     | World Wildlife Fund                                                                                                                                                              |

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### Part 3 International codes for technical & formulated pesticides\*

| Code | Term                                    | Definition                                                                                                                                                                                   |
|------|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| AB   | Grain bait                              | Special form of bait.                                                                                                                                                                        |
| AE   | Aerosol dispenser                       | A container-held formulation which is dispersed generally by a propellant as fine droplets or particles upon the actuation of a valve.                                                       |
| AL   | Any other liquid                        | A liquid not yet designated by a specific code, to be applied undiluted.                                                                                                                     |
| AP   | Any other powder                        | A powder not yet designated by a specific code, to be applied undiluted.                                                                                                                     |
| BB   | Block bait                              | Special form of bait.                                                                                                                                                                        |
| BR   | Briquette                               | Solid block designed for controlled release of active substance into water.                                                                                                                  |
| CB   | Bait concentrate                        | A solid or liquid intended for dilution before use as a bait.                                                                                                                                |
| CF   | Capsule Suspension for Seed Treatment   | A stable suspension of capsules in a fluid to be applied to the seed, either directly or after dilution.                                                                                     |
| CG   | Encapsulated granule                    | A granule with a protective or granule release-controlling coating.                                                                                                                          |
| CL   | Contact liquid or gel                   | Rodenticidal or insecticidal formulation in the form of a liquid/gel for direct application, or after dilution in the case of gels.                                                          |
| CP   | Contact powder                          | Rodenticidal or insecticidal formulation in powder form for direct application. Formerly known as tracking powder (TP).                                                                      |
| CS   | Capsule suspension                      | A stable suspension of capsules in a fluid, normally intended for dilution with water before use.                                                                                            |
| DC   | Dispersible concentrate                 | A liquid homogeneous formulation to be applied as a solid dispersion after dilution in water. (Note: there are some formulations which have characteristics intermediate between DC and EC). |
| DP   | Dustable powder                         | A free-flowing powder suitable for dusting.                                                                                                                                                  |
| DS   | Powder for dry seed treatment           | A powder for application in the dry state directly to the seed.                                                                                                                              |
| DT   | Tablet for direct application           | Formulation in the form of tablets to be applied individually and directly in the field, and/or bodies of water, without preparation of a spraying solution or dispersion.                   |
| EC   | Emulsifiable concentrate                | A liquid, homogeneous formulation to be applied as an emulsion after dilution in water.                                                                                                      |
| ED   | Electrochargeable liquid                | Special liquid formulation for electrostatic (electrodynamic) spraying.                                                                                                                      |
| EG   | Emulsifiable Granule                    | A granular formulation to be applied as an oil-in-water emulsion of the active substance after disintegration in water, which may contain water insoluble formulants.                        |
| EO   | Emulsion, water in oil                  | A fluid, heterogeneous formulation consisting of a solution of pesticide in water dispersed as fine globules in a continuous organic liquid phase.                                           |
| ES   | Emulsion for seed treatment             | A stable emulsion for application to the seed either directly or after dilution.                                                                                                             |
| EW   | Emulsion, oil in water                  | A fluid, heterogeneous formulation consisting of a solution of pesticide in an organic liquid dispersed as fine globules in a continuous water phase.                                        |
| FD   | Smoke tin                               | Special form of smoke generator.                                                                                                                                                             |
| FG   | Fine granule                            | A granule in the particle size range from 300 to 2500 µm.                                                                                                                                    |
| FK   | Smoke candle                            | Special form of smoke generator.                                                                                                                                                             |
| FP   | Smoke cartridge                         | Special form of smoke generator.                                                                                                                                                             |
| FR   | Smoke rodlet                            | Special form of smoke generator.                                                                                                                                                             |
| FS   | Flowable concentrate for seed treatment | A stable suspension for application to the seed either directly or after dilution.                                                                                                           |

\* Note: based on *Catalogue of Pesticide Formulation Types and International Coding System*. Technical Monograph No.2, GIFAP, Brussels. Revised February 1989.

|    |                                                             |                                                                                                                                                                                             |
|----|-------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| FT | Smoke tablet                                                | Special form of smoke generator.                                                                                                                                                            |
| FU | Smoke generator                                             | A combustible formulation, generally solid, which upon ignition releases the active substance(s) in the form of smoke.                                                                      |
|    | Special forms of smoke generators                           |                                                                                                                                                                                             |
|    | Smoke candle                                                | (FK)                                                                                                                                                                                        |
|    | Smoke cartridge                                             | (FP)                                                                                                                                                                                        |
|    | Smoke pellet                                                | (FW)                                                                                                                                                                                        |
|    | Smoke rodlet                                                | (FR)                                                                                                                                                                                        |
|    | Smoke tablet                                                | (FT)                                                                                                                                                                                        |
|    | Smoke tin                                                   | (FD)                                                                                                                                                                                        |
| FW | Smoke pellet                                                | Special form of smoke generator.                                                                                                                                                            |
| GA | Gas                                                         | A gas packed in pressure bottle or pressure tank.                                                                                                                                           |
| GB | Granular bait                                               | Special form of bait.                                                                                                                                                                       |
| GE | Gas generating product                                      | A formulation which generates a gas by chemical reaction.                                                                                                                                   |
| GF | Gel for Seed Treatment                                      | A homogeneous gelatinous formulation to be applied directly to the seed.                                                                                                                    |
| GG | Macrogranule                                                | A granule in the particle size range from 2000 to 6000 µm.                                                                                                                                  |
| GL | Emulsifiable gel                                            | A gelatinized formulation to be applied as an emulsion in water.                                                                                                                            |
| GP | Flo-dust                                                    | Very fine dustable powder for pneumatic application in greenhouses.                                                                                                                         |
| GR | Granule                                                     | A free-flowing solid formulation of a defined granule size range ready for use.                                                                                                             |
|    | Special forms of granules:                                  |                                                                                                                                                                                             |
|    | Encapsulated granule (CG)                                   | A granule with a protective or release-controlling coating.                                                                                                                                 |
|    | Fine granule (FG)                                           | Particle size range from 300 to 2500 µm.                                                                                                                                                    |
|    | Macrogranule (GG)                                           | Particle size range from 2000 to 6000 µm.                                                                                                                                                   |
|    | Microgranule (MG)                                           | Particle size range from 100 to 600 µm.                                                                                                                                                     |
| GS | Grease                                                      | Very viscous formulation based on oil or fat.                                                                                                                                               |
| GW | Water soluble gel                                           | A gelatinized formulation to be applied as an aqueous solution.                                                                                                                             |
| HN | Hot fogging concentrate                                     | A formulation suitable for application by hot fogging equipment, either directly or after dilution.                                                                                         |
| KK | Combi-pack solid/liquid                                     | A solid and a liquid formulation, separately contained within one outer pack, intended for simultaneous application in a tank mix.                                                          |
| KL | Combi-pack liquid/liquid                                    | Two liquid formulations, separately contained within one outer pack, intended for simultaneous application in a tank mix.                                                                   |
| KN | Cold fogging concentrate                                    | A formulation suitable for application by cold fogging equipment, either directly or after dilution.                                                                                        |
| KP | Combi-pack solid/solid                                      | Two solid formulations, separately contained within one outer pack, intended for simultaneous application in a tank mix.                                                                    |
| LA | Lacquer                                                     | Solvent-based, film-forming composition.                                                                                                                                                    |
| LS | Solution for seed treatment                                 | A clear to opalescent liquid to be applied to the seed either directly or as a solution of the active substance after dilution in water. The liquid may contain water insoluble formulants. |
| ME | Micro-emulsion                                              | A clear to opalescent, oil and water containing liquid, to be applied directly or after dilution in water, when it may form a diluted micro-emulsion or a conventional emulsion.            |
| MG | Microgranule                                                | A granule in the particle size range from 100 to 600 µm.                                                                                                                                    |
| OF | Oil miscible flowable concentrate (oil miscible suspension) | A stable suspension of active substance(s) in a fluid intended for dilution in an organic liquid before use.                                                                                |
| OL | Oil miscible liquid                                         | A liquid, homogeneous formulation to be applied as a homogeneous liquid after dilution in an organic liquid.                                                                                |
| OP | Oil dispersible powder                                      | A powder formulation to be applied as a suspension after dispersion in an organic liquid.                                                                                                   |
| PA | Paste                                                       | Water-based, film-forming composition.                                                                                                                                                      |
| PB | Plate bait                                                  | Special form of bait.                                                                                                                                                                       |
| PC | Gel or paste concentrate                                    | A solid formulation to be applied as a gel or paste after dilution with water.                                                                                                              |
| PO | Pour-on                                                     | Solution for pouring on the skin of animals in a high volume (normally more than 100 mL per animal).                                                                                        |
| PR | Plant rodlet                                                | A small rodlet, usually a few centimetres in length and a few millimetres in diameter, containing an active substance.                                                                      |
| PS | Seed coated with a pesticide                                | Self defining.                                                                                                                                                                              |
| RB | Bait (ready for use)                                        | A formulation designed to attract and be eaten by the target pests.                                                                                                                         |

|      |                                                                                                                                                   |                                                                                                                                                                                                                                                          |
|------|---------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|      | Special forms of baits:<br>Block bait (BB)<br>Grain bait (AB)<br>Granular bait (GB)<br>Plate bait (PB)<br>Scrap bait (SB)                         |                                                                                                                                                                                                                                                          |
| SA   | Spot-on                                                                                                                                           | Solution for spot application on the skin of animals in a low volume (normally less than 100 mL per animal).                                                                                                                                             |
| SB   | Scrap bait                                                                                                                                        | Special form of bait.                                                                                                                                                                                                                                    |
| SC   | Suspension concentrate (= flowable concentrate)                                                                                                   | A stable suspension of active substance(s) in a fluid, which may contain other dissolved active substance(s), intended for dilution with water before use.                                                                                               |
| SE   | Suspo-emulsion                                                                                                                                    | A fluid, heterogeneous formulation consisting of a stable dispersion of active substances in the form of solid particles and fine globules in a continuous water phase.                                                                                  |
| SG   | Water soluble granule                                                                                                                             | A formulation consisting of granules to be applied as a true solution of the active substance after dissolution in water, but which may contain insoluble inert substances.                                                                              |
| SL   | Soluble concentrate                                                                                                                               | A clear to opalescent liquid to be applied as a solution of the active substance after dilution in water. The liquid may contain water insoluble formulants.                                                                                             |
| SO   | Spreading oil                                                                                                                                     | Formulation designed to form a surface layer on application to water.                                                                                                                                                                                    |
| SP   | Water soluble powder                                                                                                                              | A powder formulation to be applied as a true solution of the active substance after dissolution in water, but which may contain insoluble inert substances.                                                                                              |
| SS   | Water soluble powder for seed treatment                                                                                                           | A powder to be dissolved in water before application to the seed.                                                                                                                                                                                        |
| ST   | Water soluble tablet                                                                                                                              | Formulation in form of tablets to be used individually, to form a solution of the active substance after disintegration in water. The formulation may contain water insoluble formulants.                                                                |
| SU   | Ultra-low volume (ULV) suspension                                                                                                                 | A suspension ready for use through ULV equipment.                                                                                                                                                                                                        |
| TB   | Tablet                                                                                                                                            | Pre-formed solids of uniform shape and dimensions, usually circular, with either flat or convex faces, the distance between faces being less than the diameter.                                                                                          |
|      | Special forms of tablets:<br>DT - tablets for direct application<br>ST - tablets for dissolution in water<br>WT - tablets for dispersion in water |                                                                                                                                                                                                                                                          |
| TC   | Technical material                                                                                                                                | A material resulting from a manufacturing process comprising the active substance, together with associated impurities. This may contain small amounts of necessary additives.                                                                           |
| TK   | Technical concentrate                                                                                                                             | A material resulting from a manufacturing process comprising the active substance, together with associated impurities. This may contain small amounts of necessary additives and appropriate diluents. For use only in the preparation of formulations. |
| (TP) | (Tracking powder)                                                                                                                                 | (Discontinued terms. Refer to CP)                                                                                                                                                                                                                        |
| UL   | Ultra-low volume (ULV) liquid                                                                                                                     | A homogeneous liquid ready for use through ULV equipment.                                                                                                                                                                                                |
| VP   | Vapour releasing product                                                                                                                          | A formulation containing one or more volatile active substances, the vapours of which are released into the air. Evaporation rate is normally controlled by using suitable formulations and/or dispensers.                                               |
| WG   | Water dispersible granules                                                                                                                        | A formulation consisting of granules to be applied after disintegration and dispersion in water.                                                                                                                                                         |
| WP   | Wettable powder                                                                                                                                   | A powder formulation to be applied as a suspension after dispersion in water.                                                                                                                                                                            |
| WS   | Water dispersible powder for slurry seed treatment                                                                                                | A powder to be dispersed at high concentration in water before application as a slurry to the seed.                                                                                                                                                      |
| WT   | Water dispersible tablet                                                                                                                          | Formulation in the form of tablets to be used individually, to form a dispersion of the active substance after disintegration in water.                                                                                                                  |
| XX   | Others                                                                                                                                            | Temporary categorization of all other formulations not listed above.                                                                                                                                                                                     |

## **CALCIUM CARBIDE**

### **LEVEL 2**

Appendix 2: Specific terms and abbreviations

## Appendix 2 Specific terms and abbreviations

### Part 1 Technical terms

|                  |                                            |
|------------------|--------------------------------------------|
| Ca <sup>++</sup> | Calcium                                    |
| Cl <sup>-</sup>  | Chloride                                   |
| K <sup>+</sup>   | Potassium                                  |
| M&K              | Maximization test of Magnusson and Kligman |
| Na <sup>+</sup>  | Sodium                                     |
| NaCl             | Sodium chloride                            |
| POEM             | Predictive Operator Exposure Model         |
| QA               | Quality Assurance                          |
| RMS              | Rapporteur Member State                    |

### Part 2 Organisations and publications

|       |                                                        |
|-------|--------------------------------------------------------|
| DGADR | Direcção-Geral de Agriculturas e Desenvolvimento Rural |
| DGPC  | Direcção-Geral de Protecção das Culturas               |

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

## **CALCIUM CARBIDE**

### **LEVEL 2**

Appendix 3: Compilation of chemical, common and code names and synonyms

### Appendix 3 Compilation of chemical, common and code names and synonyms

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

## **CALCIUM CARBIDE**

### **LEVEL 2**

#### **Appendix 4: Listing of end points**

## Appendix 4 Listing of end points

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

### Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

### Identity, Physical and Chemical Properties, Details of Uses, Further Information

Active substance (ISO Common Name) ‡

Calcium phosphide

Calcium carbide

Function (e.g. fungicide)

Repellent

Rapporteur Member State

Portugal

Co-rapporteur Member State

Not available

### Identity (Annex IIA, point 1)

Chemical name (IUPAC) ‡

Calcium phosphide

Calcium carbide

Tricalcium diphosphide

Calcium acetylide

Chemical name (CA) ‡

Calcium phosphide

Calcium carbide

CIPAC No ‡

Not available

CAS No ‡

1305-99-3

75-20-7

EC No (EINECS or ELINCS) ‡

215-142-0

200-848-3

FAO Specification (including year of publication) ‡

Not available

Minimum purity of the active substance as manufactured ‡

0.08 – 0.52 g/kg calcium phosphide

765 – 810 g/kg calcium carbide

Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured

No relevant impurities are present in the active substance as manufactured

Molecular formula ‡

Ca<sub>3</sub>P<sub>2</sub>CaC<sub>2</sub>

Molecular mass ‡

182.18 g/mol

64.10 g/mol

Structural formula ‡

$$\begin{array}{c} \text{P}^{\text{---}} \\ \text{Ca}^{++} \quad \text{Ca}^{++} \quad \text{P}^{\text{---}} \\ \text{Ca}^{++} \end{array}$$

$$\text{Ca}^{++} \quad \text{C} \equiv \text{C}^-$$

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

### Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

#### Physical and chemical properties (Annex IIA, point 2)

|                                                                          |                                                                                                                                                           |
|--------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------|
| Melting point (state purity) ‡                                           | Calcium phosphide 1600 °C (purity not stated)<br>Calcium carbide 1845 °C (800 g/kg)                                                                       |
| Boiling point (state purity) ‡                                           | Not relevant                                                                                                                                              |
| Temperature of decomposition (state purity)                              | Not applicable                                                                                                                                            |
| Appearance (state purity) ‡                                              | Calcium phosphide - red-brown crystalline powder or grey lumps (purity not stated)<br>Calcium carbide - grey solid granules with garlic odour (800 g/kg)  |
| Vapour pressure (state temperature, state purity) ‡                      | Calcium carbide - Not volatile. Stable when dry, but decomposes slowly in moist air (800 g/kg)                                                            |
| Henry's law constant ‡                                                   | Calcium phosphide - not applicable – reacts with water to produce phosphine.<br>Calcium carbide - not applicable – reacts with water to produce acetylene |
| Solubility in water (state temperature, state purity and pH) ‡           | Calcium phosphide - not applicable – reacts with water to produce phosphine.<br>Calcium carbide - not applicable – reacts with water to produce acetylene |
| Solubility in organic solvents ‡<br>(state temperature, state purity)    | Calcium carbide – very low solubility expected in organic solvents (prediction based on chemical structure)                                               |
| Surface tension ‡<br>(state concentration and temperature, state purity) | Calcium phosphide - not applicable – reacts with water to produce phosphine.<br>Calcium carbide - not applicable – reacts with water to produce acetylene |
| Partition co-efficient ‡<br>(state temperature, pH and purity)           | Calcium phosphide - not applicable – reacts with water to produce phosphine.<br>Calcium carbide - not applicable – reacts with water to produce acetylene |
| Dissociation constant (state purity) ‡                                   | Calcium phosphide - not applicable – reacts with water to produce phosphine.<br>Calcium carbide - not applicable – reacts with water to produce acetylene |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis**

UV/VIS absorption (max.) incl.  $\epsilon$  ‡  
(state purity, pH)

Calcium phosphide - not applicable – reacts with water to produce phosphine.

Calcium carbide - not applicable – reacts with water to produce acetylene

Flammability ‡ (state purity)

Calcium phosphide - Highly flammable

Calcium carbide - Highly flammable

Explosive properties ‡ (state purity)

Calcium carbide - Not explosive (purity not stated)

Oxidising properties ‡ (state purity)

Calcium carbide - Not oxidising (statement)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## Rapporteur Member State

## Month and year

## Active Substance (Name)

|          |           |                 |
|----------|-----------|-----------------|
| Portugal | June 2007 | Calcium carbide |
|----------|-----------|-----------------|

## Identity, Physical and Chemical Properties, Details of Uses, Further Information, Methods of Analysis

Summary of representative uses evaluated (*Calcium carbide*)\*

| Crop and/or situation<br>(a)                                                                                        | Member State or Country   | Product name        | F<br>G<br>or<br>I<br>(b) | Pests or Group of pests controlled<br>(c)                                  | Preparation   |                          | Application             |                                    |                           |                                              | Application rate per treatment<br>(for explanation see the text in front of this section) |                         |                                                                                             | PHI<br>(days)<br><br>(m) | Remarks |
|---------------------------------------------------------------------------------------------------------------------|---------------------------|---------------------|--------------------------|----------------------------------------------------------------------------|---------------|--------------------------|-------------------------|------------------------------------|---------------------------|----------------------------------------------|-------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------------------------------------------|--------------------------|---------|
|                                                                                                                     |                           |                     |                          |                                                                            | Type<br>(d-f) | Conc.<br>of as<br>(i)    | method<br>kind<br>(f-h) | growth<br>stage &<br>season<br>(j) | number<br>min/ max<br>(k) | interval<br>between<br>applications<br>(min) | g as/hL<br>min – max<br>(l)                                                               | water L/ha<br>min – max | g as/ha<br>min – max<br>(l)                                                                 |                          |         |
| Vegetables (NNNWW)<br>Fruit (NNNOO)<br>Ornamental plants (NNNZZ)<br>Agricultural crops (NNNAC)<br>Grassland (NNNFW) | Germany (Northern Europe) | PRONTOX Wühlmausgas | F                        | <i>Arvicola terrestris</i> (ARVCTE),<br><br><i>Talpa europaea</i> (TALPEU) | GE            | 800 g/kg Calcium carbide | covered application     | all stages                         | if/ when required         | without waiting-time                         | not applicable                                                                            | not applicable          | 4-8g/hole<br><br>16g/hole<br><br>(2-8kg/ha for a maximum infestation level of 500 holes/ha) | not required             |         |

\* For uses where the column "Remarks" is marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
- (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
- (e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
- (f) All abbreviations used must be explained
- (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
- (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant- type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxyppyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
- (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
- (k) Indicate the minimum and maximum number of application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Methods of Analysis****Methods of Analysis****Analytical methods for the active substance (Annex IIA, point 4.1)**

|                                                   |                                                                                                                                                                                                                         |
|---------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical as (analytical technique)               | Calcium phosphide - GC<br>Full description of the method and validation data are required<br>Calcium carbide – AES-ICP and gasification (DIN 53992)<br>Full description of the methods and validation data are required |
| Impurities in technical as (analytical technique) | Full description of the methods and validation data are required                                                                                                                                                        |
| Plant protection product (analytical technique)   | Calcium phosphide - GC<br>Full description of the method and validation data are required<br>Calcium carbide – AES-ICP and gasification (DIN 53992)<br>Full description of the methods and validation data are required |

**Analytical methods for residues (Annex IIA, point 4.2)****Residue definitions for monitoring purposes**

|                       |                                   |
|-----------------------|-----------------------------------|
| Food of plant origin  | No residue definition is proposed |
| Food of animal origin | No residue definition is proposed |
| Soil                  | No residue definition is proposed |
| Water surface         | No residue definition is proposed |
| drinking/ground       | No residue definition is proposed |
| Air                   | No residue definition is proposed |

**Monitoring/Enforcement methods**

|                                                                                               |                                                  |
|-----------------------------------------------------------------------------------------------|--------------------------------------------------|
| Food/feed of plant origin (analytical technique and LOQ for methods for monitoring purposes)  | Not required – no residue definition is proposed |
| Food/feed of animal origin (analytical technique and LOQ for methods for monitoring purposes) | Not required – no residue definition is proposed |
| Soil (analytical technique and LOQ)                                                           | Not required – no residue definition is proposed |
| Water (analytical technique and LOQ)                                                          | Not required – no residue definition is proposed |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Methods of Analysis**

Air (analytical technique and LOQ)

Not required – no residue definition is proposed

Body fluids and tissues (analytical technique and LOQ)

Not required – no residue definition is proposed

**Classification and proposed labelling with regard to physical and chemical data (Annex IIA, point 10)**

Active substance

RMS/peer review proposal

Calcium carbide:  
 F: Highly flammable  
 R15 – Contact with water liberates extremely flammable gases  
 S8 – Keep container dry  
 S43 – In case of fire, use sand. Never use water

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Mammalian toxicology****Impact on Human and Animal Health****Absorption, distribution, excretion and metabolism (toxicokinetics) (Annex IIA, point 5.1)**

Rate and extent of oral absorption ‡

Distribution ‡

Potential for accumulation ‡

Rate and extent of excretion ‡

Metabolism in animals ‡

Toxicologically relevant compounds ‡  
(animals and plants)Toxicologically relevant compounds ‡  
(environment)

Studies on the absorption, distribution, metabolism and excretion of calcium carbide in mammals do not exist and are not considered to be required, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the repellent use of the substance.

Calcium carbide

Calcium carbide

**Acute toxicity (Annex IIA, point 5.2)**Rat LD<sub>50</sub> oral ‡

Based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.

Rat LD<sub>50</sub> dermal ‡

Based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.

Rat LC<sub>50</sub> inhalation ‡

Not required because calcium carbide is a granule 4 – 7 mm, the particle size in dust < 50µm is smaller than 10 % w/w. Human data support classification with R37.

Xi;  
R37

Skin irritation ‡

Based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.

C;  
R35

Eye irritation ‡

Based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.

[Xi;  
R41]

Skin sensitisation ‡

Based on the measured pH of 12.48 of a 1% solution in deionised water of calcium carbide, no experiment was undertaken for humane reasons on live animals.  
Non-sensitiser according to literature data on components.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Mammalian toxicology****Short term toxicity (Annex IIA, point 5.3)**

Target / critical effect ‡

Justification for non-submission:

The complete toxicology data requirements for a food-use chemical are not required for calcium carbide since little acetylene and phosphine exposure is expected from the use pattern like repellent as such does not enter the human food chain.

Calcium carbide is introduced into the burrows or tunnels and is hydrolysed to acetylene and calcium hydroxide under the influence of soil humidity. Because of the underground application of calcium carbide, there is no contact with surface plant components or operators/workers/bystanders.

Relevant oral NOAEL ‡

No data available – not required.

Relevant dermal NOAEL ‡

No data available – not required.

Relevant inhalation NOAEL ‡

No data available – not required.

**Genotoxicity ‡ (Annex IIA, point 5.4)**

No data available – not required.

See justification for non-submission – short-term toxicity.

**Long term toxicity and carcinogenicity (Annex IIA, point 5.5)**

Target/critical effect ‡

No data available – not required. See justification for non-submission – short-term toxicity.

Relevant NOAEL ‡

No data available – not required.

Carcinogenicity ‡

No data available – not required.

**Reproductive toxicity (Annex IIA, point 5.6)****Reproduction toxicity**

Reproduction target / critical effect ‡

No data available – not required.  
See justification for non-submission – short-term toxicity.

Relevant parental NOAEL ‡

No data available – not required.

Relevant reproductive NOAEL ‡

No data available – not required.

Relevant offspring NOAEL ‡

No data available – not required.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Mammalian toxicology****Developmental toxicity**

Developmental target / critical effect ‡

|                                                                                                  |  |
|--------------------------------------------------------------------------------------------------|--|
| No data available – not required.<br>See justification for non-submission – short-term toxicity. |  |
|--------------------------------------------------------------------------------------------------|--|

Relevant maternal NOAEL ‡

|                                   |  |
|-----------------------------------|--|
| No data available – not required. |  |
|-----------------------------------|--|

Relevant developmental NOAEL ‡

|                                   |  |
|-----------------------------------|--|
| No data available – not required. |  |
|-----------------------------------|--|

**Neurotoxicity (Annex IIA, point 5.7)**

Acute neurotoxicity ‡

|                                   |  |
|-----------------------------------|--|
| No data available – not required. |  |
|-----------------------------------|--|

Repeated neurotoxicity ‡

|                                   |  |
|-----------------------------------|--|
| No data available – not required. |  |
|-----------------------------------|--|

Delayed neurotoxicity ‡

|                                   |  |
|-----------------------------------|--|
| No data available – not required. |  |
|-----------------------------------|--|

**Other toxicological studies (Annex IIA, point 5.8)**

Mechanism studies ‡

|                |
|----------------|
| Not applicable |
|----------------|

Studies performed on metabolites or impurities ‡

|                                                                                                                                                                                                   |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Literature data were submitted on metabolites: calcium hydroxide, acetylene and phosphine, on impurities: calcium oxide, and on sensitisation of silicon dioxide, carbon and calcium dihydroxide. |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Mammalian toxicology****Medical data ‡ (Annex IIA, point 5.9)**

Calcium carbide has been produced for decades at the Hart location. Up to date, some 100 people have been exposed to calcium carbide during production. Previously it was significantly more and the production conditions were less favourable. During these years and in previous years according to the records, no specific effects damaging to health of calcium carbide have been observed.

From time to time skin and eye irritation were apparent among workers. As a rule these were associated with heavy perspiration particularly when working with ovens. No such effects were known during reconditioning and maintenance.

Because of eye irritation, which reduces in a few hours after ocular rinsing and non-specific therapy with Bepanthen eye cream, some 20 treatments were carried out annually. Due to skin irritation, which similarly reduced rapidly following short-term topical cortisone therapy, there were ca. 15 treatments annually. The high number results from the urgent requirements of factory management to medical report even such small incidents around the clock. In the years of his practice, two workers were moved by mutual agreement from carbide production, due to recurrent conjunctival inflammation. Routine occupational medical examinations were offered to workers every three years. The main emphasis being on noise, dust masks, driving ability, working in hot conditions and fully continuous shift work. A specific examination for calcium carbide does not exist naturally. Furthermore, during these comprehensive examinations, which include a hearing test, sight test, lung function, ECG under exercise, blood and urine examinations, no dust or carbide-related signs appeared.

**Summary (Annex IIA, point 5.10)**

ADI ‡

AOEL ‡

ARfD ‡

| Value                         | Study | Safety factor |
|-------------------------------|-------|---------------|
| Not allocated – not necessary |       |               |
| Not allocated – not necessary |       |               |
| Not allocated – not necessary |       |               |

**Dermal absorption ‡ (Annex IIIA, point 7.3)**

Formulation (PRONTOX Wühlmausgas)

No data available – not required.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Mammalian toxicology****Exposure scenarios (Annex IIIA, point 7.2)**

Operator

PRONTOX Wühlmausgas represents a ready-to-use repellent, which is placed underground into target animal runs and tunnels by means of a spoon or another aid, designed to both an applicator and a dosage measuring system. Exposure is considered negligible; skin contact is effectively prevented by wearing general-purpose protective clothing, gloves and eye/face protection.

Workers

No exposure is anticipated.

Bystanders

No exposure is anticipated.

**Classification and proposed labelling with regard to toxicological data (Annex IIA, point 10)**

Substance classified (name)

RMS/peer review proposal

C Corrosive

R35 Causes severe burns.

R37 Irritating to respiratory system

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Residues****Metabolism in plants (Annex IIA, point 6.1 and 6.7, Annex IIIA, point 8.1 and 8.6)**

Plant groups covered

Rotational crops

Metabolism in rotational crops similar to metabolism in primary crops?

Processed commodities

Residue pattern in processed commodities similar to residue pattern in raw commodities?

Plant residue definition for monitoring

Plant residue definition for risk assessment

Conversion factor (monitoring to risk assessment)

Justification for non-submission:

The submission of data or the performance of a test on metabolism, distribution and expression of residues in plants of calcium carbide is not required, since no residues of calcium carbide in plants are expected, due to the rapid hydrolysis of the active substance in the soil generating acetylene and calcium hydroxide.

**Metabolism in livestock (Annex IIA, point 6.2 and 6.7, Annex IIIA, point 8.1 and 8.6)**

Animals covered

Time needed to reach a plateau concentration in milk and eggs

Animal residue definition for monitoring

Animal residue definition for risk assessment

Conversion factor (monitoring to risk assessment)

Metabolism in rat and ruminant similar (yes/no)

Fat soluble residue: (yes/no)

Justification for non-submission:

The submission of data or the performance of a test on metabolism, distribution and expression of residues in livestock of calcium carbide is not required, since no residues of calcium carbide in plants are expected, due to the rapid hydrolysis of the active substance in the soil generating acetylene and calcium hydroxide

**Residues in succeeding crops (Annex IIA, point 6.6, Annex IIIA, point 8.5)**

not applicable

**Stability of residues (Annex IIA, point 6 introduction, Annex IIIA, point 8 Introduction)**

not applicable

Residues from livestock feeding studies (Annex IIA, point 6.4, Annex IIIA, point 8.3)

Expected intakes by livestock  $\geq 0.1$  mg/kg diet (dry weight basis) (yes/no - If yes, specify the level)

| Ruminant:                                    | Poultry:       | Pig:           |
|----------------------------------------------|----------------|----------------|
| Conditions of requirement of feeding studies |                |                |
| not applicable                               | not applicable | not applicable |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Residues**

Potential for accumulation (yes/no):

Metabolism studies indicate potential level of residues  $\geq 0.01$  mg/kg in edible tissues (yes/no)

Muscle

Liver

Kidney

Fat

Milk

Eggs

|                                                                                                 |                |                |
|-------------------------------------------------------------------------------------------------|----------------|----------------|
| not applicable                                                                                  | not applicable | not applicable |
| not applicable                                                                                  | not applicable | not applicable |
| Feeding studies (Specify the feeding rate in cattle and poultry studies considered as relevant) |                |                |
| Residue levels in matrices : Mean (max) mg/kg                                                   |                |                |
| not applicable                                                                                  | not applicable | not applicable |
| not applicable                                                                                  | not applicable | not applicable |
| not applicable                                                                                  | not applicable | not applicable |
| not applicable                                                                                  | not applicable | not applicable |
| not applicable                                                                                  |                |                |
|                                                                                                 | not applicable |                |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

## List of end points

EPCO Manual E4 - rev. 4 (September 2005)

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

## Residues

Summary of residues data according to the representative uses on raw agricultural commodities and feedingstuffs (Annex IIA, point 6.3, Annex IIIA, point 8.2)

| Crop           | Northern or Mediterranean Region, field or glasshouse, and any other useful information | Trials results relevant to the representative uses<br><br>(a) | Recommendation/comments | MRL estimated from trials according to the representative use | HR<br><br>(c) | STMR<br><br>(b) |
|----------------|-----------------------------------------------------------------------------------------|---------------------------------------------------------------|-------------------------|---------------------------------------------------------------|---------------|-----------------|
| not applicable |                                                                                         |                                                               |                         |                                                               |               |                 |
|                |                                                                                         |                                                               |                         |                                                               |               |                 |
|                |                                                                                         |                                                               |                         |                                                               |               |                 |
|                |                                                                                         |                                                               |                         |                                                               |               |                 |
|                |                                                                                         |                                                               |                         |                                                               |               |                 |

(a) Numbers of trials in which particular residue levels were reported *e.g.* 3 x <0.01, 1 x 0.01, 6 x 0.02, 1 x 0.04, 1 x 0.08, 2 x 0.1, 2 x 0.15, 1 x 0.17

(b) Supervised Trials Median Residue *i.e.* the median residue level estimated on the basis of supervised trials relating to the representative use

(c) Highest residue

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Residues****Consumer risk assessment (Annex IIA, point 6.9, Annex IIIA, point 8.8)**

|                                                                                       |                |
|---------------------------------------------------------------------------------------|----------------|
| ADI                                                                                   | not applicable |
| TMDI (% ADI) according to WHO European diet                                           | not applicable |
| TMDI (% ADI) according to national (to be specified) diets                            | not applicable |
| IEDI (WHO European Diet) (% ADI)                                                      | not applicable |
| NEDI (specify diet) (% ADI)                                                           | not applicable |
| Factors included in IEDI and NEDI                                                     | not applicable |
| ARfD                                                                                  | not applicable |
| IESTI (% ARfD)                                                                        | not applicable |
| NESTI (% ARfD) according to national (to be specified) large portion consumption data | not applicable |
| Factors included in IESTI and NESTI                                                   | not applicable |

**Processing factors (Annex IIA, point 6.5, Annex IIIA, point 8.4)**

| Crop/ process/ processed product | Number of studies | Processing factors |              | Amount transferred (%)<br>(Optional) |
|----------------------------------|-------------------|--------------------|--------------|--------------------------------------|
|                                  |                   | Transfer factor    | Yield factor |                                      |
| not applicable                   |                   |                    |              |                                      |
|                                  |                   |                    |              |                                      |
|                                  |                   |                    |              |                                      |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Residues****Proposed MRLs** (Annex IIA, point 6.7, Annex IIIA, point 8.6)

not applicable

.....

.....

.....

.....

|  |
|--|
|  |
|  |
|  |
|  |

When the MRL is proposed at the LOQ, this should be annotated by an asterisk after the figure.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment****Route of degradation (aerobic) in soil (Annex IIA, point 7.1.1.1)**

|                                                                                                       |                     |
|-------------------------------------------------------------------------------------------------------|---------------------|
| Mineralization after 100 days ‡                                                                       | No study available. |
| Non-extractable residues after 100 days ‡                                                             | No study available. |
| Metabolites requiring further consideration ‡<br>- name and/or code, % of applied (range and maximum) | No study available. |

**Route of degradation in soil - Supplemental studies (Annex IIA, point 7.1.1.2)**

|                                                                                                                                   |                                      |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| Anaerobic degradation ‡                                                                                                           |                                      |
| Mineralization after 100 days                                                                                                     | No study available.<br>Not required. |
| Non-extractable residues after 100 days                                                                                           | No study available.<br>Not required. |
| Metabolites that may require further consideration<br>for risk assessment - name and/or code, % of<br>applied (range and maximum) | No study available.<br>Not required. |
| Soil photolysis ‡                                                                                                                 |                                      |
| Metabolites that may require further consideration<br>for risk assessment - name and/or code, % of<br>applied (range and maximum) | No study available.<br>Not required. |

**Rate of degradation in soil (Annex IIA, point 7.1.1.2, Annex IIIA, point 9.1.1)**

## Laboratory studies ‡

| Parent                | Aerobic conditions |    |                    |                                        |                                            |                       |                       |
|-----------------------|--------------------|----|--------------------|----------------------------------------|--------------------------------------------|-----------------------|-----------------------|
| Soil type             | X <sup>4</sup>     | pH | t. °C / % MWHC     | DT <sub>50</sub> /DT <sub>90</sub> (d) | DT <sub>50</sub> (d)<br>20 °C<br>pF2/10kPa | St. (r <sup>2</sup> ) | Method of calculation |
| Geometric mean/median |                    |    | No study available |                                        |                                            |                       |                       |

| Met 1                 | Aerobic conditions |    |                    |                                         |                                       |                                            |                       |                       |
|-----------------------|--------------------|----|--------------------|-----------------------------------------|---------------------------------------|--------------------------------------------|-----------------------|-----------------------|
| Soil type             | X <sup>1</sup>     | pH | t. °C / % MWHC     | DT <sub>50</sub> / DT <sub>90</sub> (d) | f. f. k <sub>dp</sub> /k <sub>f</sub> | DT <sub>50</sub> (d)<br>20 °C<br>pF2/10kPa | St. (r <sup>2</sup> ) | Method of calculation |
| Geometric mean/median |                    |    | No study available |                                         |                                       |                                            |                       |                       |

<sup>4</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment**

## Field studies ‡

| Parent                                                 | Aerobic conditions               |                |    |            |                             |                             |                       |                            |                       |
|--------------------------------------------------------|----------------------------------|----------------|----|------------|-----------------------------|-----------------------------|-----------------------|----------------------------|-----------------------|
| Soil type (indicate if bare or cropped soil was used). | Location (country or USA state). | X <sup>1</sup> | pH | Depth (cm) | DT <sub>50</sub> (d) actual | DT <sub>90</sub> (d) actual | St. (r <sup>2</sup> ) | DT <sub>50</sub> (d) Norm. | Method of calculation |
| Geometric mean/median                                  |                                  |                |    |            | No study available          |                             |                       |                            |                       |

| Met 1                 | Aerobic conditions |  |    |            |                             |                             |                       |                            |                       |
|-----------------------|--------------------|--|----|------------|-----------------------------|-----------------------------|-----------------------|----------------------------|-----------------------|
| Soil type             | Location           |  | pH | Depth (cm) | DT <sub>50</sub> (d) actual | DT <sub>90</sub> (d) actual | St. (r <sup>2</sup> ) | DT <sub>50</sub> (d) Norm. | Method of calculation |
| Geometric mean/median |                    |  |    |            | No study available          |                             |                       |                            |                       |

pH dependence ‡  
(yes / no) (if yes type of dependence)

No data available

Soil accumulation and plateau concentration ‡

No data available

## Laboratory studies ‡

| Parent                | Anaerobic conditions |    |                    |                                         |                                            |                       |                       |
|-----------------------|----------------------|----|--------------------|-----------------------------------------|--------------------------------------------|-----------------------|-----------------------|
| Soil type             | X <sup>5</sup>       | pH | t. °C / % MWHC     | DT <sub>50</sub> / DT <sub>90</sub> (d) | DT <sub>50</sub> (d)<br>20 °C<br>pF2/10kPa | St. (r <sup>2</sup> ) | Method of calculation |
| Geometric mean/median |                      |    | No study available |                                         |                                            |                       |                       |

| Met 1                 | Anaerobic conditions |    |                    |                                            |                                          |                                           |                          |                          |
|-----------------------|----------------------|----|--------------------|--------------------------------------------|------------------------------------------|-------------------------------------------|--------------------------|--------------------------|
| Soil type             | X <sup>1</sup>       | pH | t. °C / %<br>MWHC  | DT <sub>50</sub> / DT <sub>90</sub><br>(d) | f. f.<br>k <sub>dp</sub> /k <sub>f</sub> | DT <sub>50</sub> (d)<br>20°C<br>pF2/10kPa | St.<br>(r <sup>2</sup> ) | Method of<br>calculation |
| Geometric mean/median |                      |    | No study available |                                            |                                          |                                           |                          |                          |

**Soil adsorption/desorption (Annex IIA, point 7.1.2)**

| Parent ‡               |      |         |                       |                        |                       |                         |     |  |
|------------------------|------|---------|-----------------------|------------------------|-----------------------|-------------------------|-----|--|
| Soil Type              | OC % | Soil pH | K <sub>d</sub> (mL/g) | K <sub>oc</sub> (mL/g) | K <sub>f</sub> (mL/g) | K <sub>foc</sub> (mL/g) | 1/n |  |
| Arithmetic mean/median |      |         |                       |                        |                       |                         |     |  |

<sup>5</sup> X This column is reserved for any other property that is considered to have a particular impact on the degradation rate.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment**

|                          |                    |
|--------------------------|--------------------|
| pH dependence, Yes or No | No study available |
|--------------------------|--------------------|

|                           |      |         |              |                    |              |                |     |
|---------------------------|------|---------|--------------|--------------------|--------------|----------------|-----|
| Metabolite 1 ‡            |      |         |              |                    |              |                |     |
| Soil Type                 | OC % | Soil pH | Kd<br>(mL/g) | Koc<br>(mL/g)      | Kf<br>(mL/g) | Kfoc<br>(mL/g) | 1/n |
| Arithmetic mean/median    |      |         |              |                    |              |                |     |
| pH dependence (yes or no) |      |         |              | No study available |              |                |     |

**Mobility in soil (Annex IIA, point 7.1.3, Annex IIIA, point 9.1.2)**

Column leaching ‡

No study available.

No data required.

No study available

Aged residues leaching ‡

No study available

Lysimeter/ field leaching studies ‡

No study available

**PEC (soil) (Annex IIIA, point 9.1.3)**

Parent

Not calculated

Method of calculation

Application data

**PEC<sub>(s)</sub>**  
(mg/kg)

Initial

Short term 24h

2d

4d

Long term 7d

28d

50d

100d

| Single application<br>Actual | Single application<br>Time weighted<br>average | Multiple application<br>Actual | Multiple application<br>Time weighted<br>average |
|------------------------------|------------------------------------------------|--------------------------------|--------------------------------------------------|
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |
|                              |                                                |                                |                                                  |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment**

|                                     |                              |                                             |                                |                                               |
|-------------------------------------|------------------------------|---------------------------------------------|--------------------------------|-----------------------------------------------|
| <b>PEC<sub>(s)</sub></b><br>(mg/kg) | Single application<br>Actual | Single application<br>Time weighted average | Multiple application<br>Actual | Multiple application<br>Time weighted average |
| Plateau concentration               | x mg/kg after n yr           |                                             |                                |                                               |

|                       |                |
|-----------------------|----------------|
| Metabolite I          | Not calculated |
| Method of calculation |                |
| Application data      |                |

|                                     |                              |                                             |                                |                                               |
|-------------------------------------|------------------------------|---------------------------------------------|--------------------------------|-----------------------------------------------|
| <b>PEC<sub>(s)</sub></b><br>(mg/kg) | Single application<br>Actual | Single application<br>Time weighted average | Multiple application<br>Actual | Multiple application<br>Time weighted average |
| Initial                             |                              |                                             |                                |                                               |
| Short term 24h                      |                              |                                             |                                |                                               |
| 2d                                  |                              |                                             |                                |                                               |
| 4d                                  |                              |                                             |                                |                                               |
| Long term 7d                        |                              |                                             |                                |                                               |
| 28d                                 |                              |                                             |                                |                                               |
| 50d                                 |                              |                                             |                                |                                               |
| 100d                                |                              |                                             |                                |                                               |
| Plateau concentration               | x mg/kg after n yr           |                                             |                                |                                               |

**Route and rate of degradation in water (Annex IIA, point 7.2.1)**

|                                                                            |                                       |
|----------------------------------------------------------------------------|---------------------------------------|
| Hydrolytic degradation of the active substance and metabolites > 10 % ‡    | pH 5: No study available              |
|                                                                            | pH 7: No study available              |
|                                                                            | pH 9: No study available              |
| Photolytic degradation of active substance and metabolites above 10 % ‡    | DT <sub>50</sub> : No study available |
| Quantum yield of direct phototransformation in water at $\lambda > 290$ nm | No study available                    |
| Readily biodegradable ‡<br>(yes/no)                                        | No study available                    |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment****Degradation in water / sediment**

| Parent                  | Distribution (eg max in water $x$ after $n$ d. Max. sed $x$ % after $n$ d) |        |       |                                               |                       |                                          |                       |                                        |                       |                       |
|-------------------------|----------------------------------------------------------------------------|--------|-------|-----------------------------------------------|-----------------------|------------------------------------------|-----------------------|----------------------------------------|-----------------------|-----------------------|
| Water / sediment system | pH water phase                                                             | pH sed | t. °C | DT <sub>50</sub> -DT <sub>90</sub> whole sys. | St. (r <sup>2</sup> ) | DT <sub>50</sub> -DT <sub>90</sub> water | St. (r <sup>2</sup> ) | DT <sub>50</sub> -DT <sub>90</sub> sed | St. (r <sup>2</sup> ) | Method of calculation |
| No study available      |                                                                            |        |       |                                               |                       |                                          |                       |                                        |                       |                       |
| Geometric mean/median   |                                                                            |        |       |                                               |                       |                                          |                       |                                        |                       |                       |

| Metabolite 1                                | Distribution (eg max in water $x$ after $n$ d. Max. sed $x$ % after $n$ d) |        |                                                       |                                               |                                                        |                                          |                                                                           |                                         |                       |                       |
|---------------------------------------------|----------------------------------------------------------------------------|--------|-------------------------------------------------------|-----------------------------------------------|--------------------------------------------------------|------------------------------------------|---------------------------------------------------------------------------|-----------------------------------------|-----------------------|-----------------------|
| Water / sediment system                     | pH water phase                                                             | pH sed | t. °C                                                 | DT <sub>50</sub> -DT <sub>90</sub> whole sys. | St. (r <sup>2</sup> )                                  | DT <sub>50</sub> -DT <sub>90</sub> water | r <sup>2</sup>                                                            | DT <sub>50</sub> - DT <sub>90</sub> sed | St. (r <sup>2</sup> ) | Method of calculation |
| No study available                          |                                                                            |        |                                                       |                                               |                                                        |                                          |                                                                           |                                         |                       |                       |
| Geometric mean/median                       |                                                                            |        |                                                       |                                               |                                                        |                                          |                                                                           |                                         |                       |                       |
| Mineralization and non extractable residues |                                                                            |        |                                                       |                                               |                                                        |                                          |                                                                           |                                         |                       |                       |
| Water / sediment system                     | pH water phase                                                             | pH sed | Mineralization $x$ % after $n$ d. (end of the study). |                                               | Non-extractable residues in sed. max $x$ % after $n$ d |                                          | Non-extractable residues in sed. max $x$ % after $n$ d (end of the study) |                                         |                       |                       |
| No study available                          |                                                                            |        |                                                       |                                               |                                                        |                                          |                                                                           |                                         |                       |                       |

**PEC (surface water) and PEC sediment (Annex IIIA, point 9.2.3)**

|                                                  |                 |
|--------------------------------------------------|-----------------|
| Parent                                           | Not calculated. |
| Parameters used in FOCUSsw step 1 and 2          | Not calculated. |
| Parameters used in FOCUSsw step 3 (if performed) | Not calculated. |
| Application rate                                 |                 |

| FOCUS STEP 1 Scenario | Day after overall maximum | PEC <sub>SW</sub> (µg/L) |     | PEC <sub>SED</sub> (µg/kg) |     |
|-----------------------|---------------------------|--------------------------|-----|----------------------------|-----|
|                       |                           | Actual                   | TWA | Actual                     | TWA |
|                       | 0 h                       |                          |     |                            |     |
|                       | 24 h                      |                          |     |                            |     |
|                       | 2 d                       |                          |     |                            |     |
|                       | 4 d                       |                          |     |                            |     |
|                       | 7 d                       |                          |     |                            |     |
|                       | 14 d                      |                          |     |                            |     |
|                       | 21 d                      |                          |     |                            |     |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment**

| FOCUS STEP 1<br>Scenario | Day after<br>overall<br>maximum | PEC <sub>SW</sub> (µg/L) |     | PEC <sub>SED</sub> (µg/kg) |     |
|--------------------------|---------------------------------|--------------------------|-----|----------------------------|-----|
|                          |                                 | Actual                   | TWA | Actual                     | TWA |
|                          | 28 d                            |                          |     |                            |     |
|                          | 42 d                            |                          |     |                            |     |

Metabolite X

Parameters used in FOCUS<sub>SW</sub> step 1 and 2Parameters used in FOCUS<sub>SW</sub> step 3 (if performed)

Application rate

Main routes of entry

Not calculated.

Not calculated.

| FOCUS STEP 1<br>Scenario | Day after<br>overall<br>maximum | PEC <sub>SW</sub> (µg/L) |     | PEC <sub>SED</sub> (µg/kg) |     |
|--------------------------|---------------------------------|--------------------------|-----|----------------------------|-----|
|                          |                                 | Actual                   | TWA | Actual                     | TWA |
|                          | 0h                              |                          |     |                            |     |
|                          | 24h                             |                          |     |                            |     |
|                          | 2d                              |                          |     |                            |     |
|                          | 4d                              |                          |     |                            |     |
|                          | 7d                              |                          |     |                            |     |
|                          | 14d                             |                          |     |                            |     |
|                          | 21d                             |                          |     |                            |     |
|                          | 28d                             |                          |     |                            |     |
|                          | 42d                             |                          |     |                            |     |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment****PEC (ground water) (Annex IIIA, point 9.2.1)**

Method of calculation and type of study (e.g. modelling, field leaching, lysimeter )

Not calculated.

Application rate

Not calculated.

**PEC(gw) - FOCUS modelling results (80<sup>th</sup> percentile annual average concentration at 1m)**

| Model /Crop | Scenario     | Parent<br>(µg/L) | Metabolite (µg/L) |   |   |
|-------------|--------------|------------------|-------------------|---|---|
|             |              |                  | 1                 | 2 | 3 |
|             | Chateaudun   | -                | -                 | - | - |
|             | Hamburg      | -                | -                 | - | - |
|             | Jokioinen    | -                | -                 | - | - |
|             | Kremsmunster | -                | -                 | - | - |
|             | Okehampton   | -                | -                 | - | - |
|             | Piacenza     | -                | -                 | - | - |
|             | Porto        | -                | -                 | - | - |
|             | Sevilla      | -                | -                 | - | - |
|             | Thiva        | -                | -                 | - | - |

**PEC<sub>(gw)</sub> From lysimeter / field studies**

| Parent                | 1 <sup>st</sup> year | 2 <sup>nd</sup> year | 3 <sup>rd</sup> year |
|-----------------------|----------------------|----------------------|----------------------|
| Annual average (µg/L) | No study available   |                      |                      |

| Metabolite X          | 1 <sup>st</sup> year | 2 <sup>nd</sup> year | 3 <sup>rd</sup> year |
|-----------------------|----------------------|----------------------|----------------------|
| Annual average (µg/L) | No study available   |                      |                      |

**Fate and behaviour in air (Annex IIA, point 7.2.2, Annex III, point 9.3)**

|                                              |                     |
|----------------------------------------------|---------------------|
| Direct photolysis in air ‡                   | No study available. |
|                                              | No data requested.  |
| Quantum yield of direct phototransformation  | No study available. |
|                                              | No data requested.  |
| Photochemical oxidative degradation in air ‡ | No study available. |
|                                              | No data requested.  |
| Volatilisation ‡                             | No study available. |
|                                              | No data requested.  |
|                                              | No study available. |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Fate and behaviour in the environment**

Metabolites

No data requested.

No study available.

No data requested.

**PEC (air)**

Method of calculation

Not calculated

**PEC<sub>(a)</sub>**

Maximum concentration

Not calculated

**Residues requiring further assessment**

Environmental occurring metabolite requiring further assessment by other disciplines (toxicology and ecotoxicology).

Soil: none

Surface Water: none

Sediment: none

Ground water: none

Air: none

**Monitoring data, if available (Annex IIA, point 7.4)**

Soil (indicate location and type of study)

No study available

Surface water (indicate location and type of study)

No study available

Ground water (indicate location and type of study)

No study available

Air (indicate location and type of study)

No study available

**Points pertinent to the classification and proposed labelling with regard to fate and behaviour data**

|  |
|--|
|  |
|--|

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology****Effects on terrestrial vertebrates (Annex IIA, point 8.1, Annex IIIA, points 10.1 and 10.3)**

| Species                          | Test substance | Time scale | End point<br>(mg/kg<br>bw/day) | End point<br>(mg/kg feed) |
|----------------------------------|----------------|------------|--------------------------------|---------------------------|
| Birds ‡                          |                |            |                                |                           |
| Indicate species.                | a.s.           | Acute      | No studies submitted           |                           |
|                                  | Preparation    | Acute      |                                |                           |
|                                  | Metabolite 1   | Acute      |                                |                           |
|                                  | a.s.           | Short-term |                                |                           |
|                                  | a.s.           | Long-term  |                                |                           |
| Mammals ‡                        |                |            |                                |                           |
| Indicate species.                | a.s.           | Acute      | No studies submitted           |                           |
|                                  | Preparation    | Acute      |                                |                           |
|                                  | Metabolite 1   | Acute      |                                |                           |
|                                  | a.s.           | Long-term  |                                |                           |
| Additional higher tier studies ‡ |                |            |                                |                           |
| No studies were submitted        |                |            |                                |                           |
| Not required.                    |                |            |                                |                           |

**Toxicity/exposure ratios for terrestrial vertebrates (Annex IIIA, points 10.1 and 10.3)**

## Crop and application rate

| Crop and application rate               |            |                |                  |                               |
|-----------------------------------------|------------|----------------|------------------|-------------------------------|
| Indicator species/Category <sup>2</sup> | Time scale | ETE            | TER <sup>1</sup> | Annex VI Trigger <sup>3</sup> |
| Tier 1 (Birds)                          |            |                |                  |                               |
|                                         | Acute      | Not calculated |                  | 10                            |
|                                         | Short-term |                |                  | 10                            |
|                                         | Long-term  |                |                  | 5                             |
| Higher tier refinement (Birds)          |            |                |                  |                               |
|                                         | Acute      | Not calculated |                  | 10                            |
|                                         | Short-term |                |                  | 10                            |
|                                         | Long-term  |                |                  | 5                             |
| Tier 1 (Mammals)                        |            |                |                  |                               |
|                                         | Acute      | Not calculated |                  | 10                            |
|                                         | Long-term  |                |                  | 5                             |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology**

| Indicator species/Category <sup>2</sup> | Time scale | ETE            | TER <sup>1</sup> | Annex VI Trigger <sup>3</sup> |
|-----------------------------------------|------------|----------------|------------------|-------------------------------|
| Higher tier refinement (Mammals)        |            |                |                  |                               |
|                                         | Acute      | Not calculated |                  | 10                            |
|                                         | Long-term  |                |                  | 5                             |

<sup>1</sup> in higher tier refinement provide brief details of any refinements used (e.g., residues, PT, PD or AV)

<sup>2</sup> for cereals indicate if it is early or late crop stage

<sup>3</sup> If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance (e.g. many single species data), it should appear in this column.

**Toxicity data for aquatic species (most sensitive species of each group) (Annex IIA, point 8.2, Annex IIIA, point 10.2)**

| Group                       | Test substance | Time-scale<br>(Test type) | End point                                   | Toxicity <sup>1</sup><br>(mg/L) |
|-----------------------------|----------------|---------------------------|---------------------------------------------|---------------------------------|
| Laboratory tests ‡          |                |                           |                                             |                                 |
| Fish                        |                |                           |                                             |                                 |
| <i>Indicate species.</i>    | a.s.           | 96 hr (flow-through)      | Mortality, EC <sub>50</sub>                 | > 50                            |
|                             | a.s.           | 28 d (static)             | Growth NOEC                                 | -                               |
|                             | Preparation    | 96 hr (flow-through)      | Mortality, EC <sub>50</sub>                 | > 50                            |
|                             | Preparation    | 28 d (flow-through)       | Growth NOEC                                 | -                               |
|                             | Metabolite 1   | 96 hr (flow-through)      | Mortality, EC <sub>50</sub>                 | -                               |
| Aquatic invertebrate        |                |                           |                                             |                                 |
| <i>Indicate species.</i>    | a.s.           | 48 h (static)             | Mortality, EC <sub>50</sub>                 | 4.62                            |
|                             | a.s.           | 21 d (static)             | Reproduction, NOEC                          | -                               |
|                             | Preparation    | 48 h (static)             | Mortality, EC <sub>50</sub>                 | 4.62                            |
|                             | Preparation    | 21 d (static)             | Reproduction, NOEC                          | -                               |
|                             | Metabolite 1   | 48 h (static)             | Mortality, EC <sub>50</sub>                 | -                               |
| Sediment dwelling organisms |                |                           |                                             |                                 |
| <i>Indicate species.</i>    | a.s.           | 28 d (static)             | NOEC                                        | -                               |
|                             | Metabolite 2   | 28 d (static)             | NOEC                                        | -                               |
| Algae                       |                |                           |                                             |                                 |
| <i>Indicate species.</i>    | a.s.           | 72 h (static)             | Biomass: E <sub>b</sub> C <sub>50</sub>     | 12.4                            |
|                             |                |                           | Growth rate: E <sub>r</sub> C <sub>50</sub> | 46.5                            |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology**

| Group                       | Test substance | Time-scale<br>(Test type) | End point                                                                              | Toxicity <sup>1</sup><br>(mg/L) |
|-----------------------------|----------------|---------------------------|----------------------------------------------------------------------------------------|---------------------------------|
|                             | Preparation    | 72 h (static)             | Biomass: E <sub>b</sub> C <sub>50</sub><br>Growth rate: E <sub>r</sub> C <sub>50</sub> | 12.4<br>46.5                    |
|                             | Metabolite 1   | 72 h (static)             | Biomass: E <sub>b</sub> C <sub>50</sub><br>Growth rate: E <sub>r</sub> C <sub>50</sub> | -<br>-                          |
| Higher plant                |                |                           |                                                                                        |                                 |
| <i>Indicate species.</i>    | a.s.           | 14 d (static)             | Fronds, EC <sub>50</sub>                                                               | -                               |
|                             | Preparation    | 14 d (static)             | Fronds, EC <sub>50</sub>                                                               | -                               |
|                             | Metabolite 1   | 14 d (static)             | Fronds, EC <sub>50</sub>                                                               | -                               |
| Microcosm or mesocosm tests |                |                           |                                                                                        |                                 |
| Not required                |                |                           |                                                                                        |                                 |

<sup>1</sup> indicate whether based on nominal (<sub>nom</sub>) or mean measured concentrations (<sub>mm</sub>). In the case of preparations indicate whether end points are presented as units of preparation or a.s.

**Toxicity/exposure ratios for the most sensitive aquatic organisms (Annex IIIA, point 10.2)****FOCUS Step1**

Crop and application rate

| Test substance                                            | Organism                                    | Toxicity<br>end point<br>(mg/L) | Time<br>scale | PEC <sub>i</sub> | PEC <sub>twa</sub> | TER | Annex VI<br>Trigger <sup>1</sup> |
|-----------------------------------------------------------|---------------------------------------------|---------------------------------|---------------|------------------|--------------------|-----|----------------------------------|
| a.s.                                                      | Fish                                        | >50                             | Acute         |                  |                    |     | 100                              |
| a.s.                                                      | Fish                                        | -                               | Chronic       |                  |                    |     | 10                               |
| a.s.                                                      | Aquatic<br>invertebrates                    | 4.62                            | Acute         |                  |                    |     | 100                              |
| a.s.                                                      | Aquatic<br>invertebrates                    | -                               | Chronic       |                  |                    |     | 10                               |
| a.s.                                                      | Algae                                       | 12.4                            | Chronic       |                  |                    |     | 10                               |
| a.s.                                                      | Higher plants <sup>2</sup>                  | -                               | Chronic       |                  |                    |     | 10                               |
| a.s.                                                      | Sediment-dwelling <sup>3</sup><br>organisms | -                               | Chronic       |                  |                    |     | 10                               |
| Metabolites                                               | Relevant organisms                          | -                               |               |                  |                    |     |                                  |
| Product<br>(calcium carbide<br>technical<br>unformulated) | Relevant organisms                          | 4.62                            |               |                  |                    |     |                                  |

<sup>1</sup> If the Annex VI Trigger value has been adjusted during the risk assessment of the active substance, it should appear in this column. E.g. if it is agreed during the risk assessment of mesocosm, that a trigger value of 5 is required, it should appear as a minimum requirement to MS in relation to product approval.

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology**<sup>2</sup> only required for herbicides<sup>3</sup> consider the need for PEC<sub>sw</sub> and PEC<sub>sed</sub> and indicate which has been used

| Bioconcentration                                                                |                      |             |             |             |
|---------------------------------------------------------------------------------|----------------------|-------------|-------------|-------------|
|                                                                                 | Active substance     | Metabolite1 | Metabolite2 | Metabolite3 |
| logP <sub>O/W</sub>                                                             | No studies submitted |             |             |             |
| Bioconcentration factor (BCF) <sup>1</sup> ‡                                    |                      |             |             |             |
| Annex VI Trigger for the bioconcentration factor                                |                      |             |             |             |
| Clearance time (days) (CT <sub>50</sub> )                                       |                      |             |             |             |
| (CT <sub>90</sub> )                                                             |                      |             |             |             |
| Level and nature of residues (%) in organisms after the 14 day depuration phase |                      |             |             |             |

<sup>1</sup> only required if log P<sub>O/W</sub> > 3.\* based on total <sup>14</sup>C or on specific compounds**Effects on honeybees (Annex IIA, point 8.3.1, Annex IIIA, point 10.4)**

| Test substance            | Acute oral toxicity (LD <sub>50</sub> µg/bee) | Acute contact toxicity (LD <sub>50</sub> µg/bee) |
|---------------------------|-----------------------------------------------|--------------------------------------------------|
| a.s. ‡                    | No studies submitted                          |                                                  |
| Preparation <sup>1</sup>  |                                               |                                                  |
| Metabolite 1              |                                               |                                                  |
| Field or semi-field tests |                                               |                                                  |
| not required              |                                               |                                                  |

<sup>1</sup> for preparations indicate whether end point is expressed in units of a.s. or preparation**Hazard quotients for honey bees (Annex IIIA, point 10.4)**

## Crop and application rate

| Test substance | Route   | Hazard quotient | Annex VI Trigger |
|----------------|---------|-----------------|------------------|
| a.s.           | Contact | Not calculated  | 50               |
| a.s.           | oral    |                 | 50               |
| Preparation    | Contact |                 | 50               |
| Preparation    | oral    |                 | 50               |

**Effects on other arthropod species (Annex IIA, point 8.3.2, Annex IIIA, point 10.5)**

Laboratory tests with standard sensitive species

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology**

| Species                        | Test Substance | End point | Effect (LR <sub>50</sub> g/ha <sup>1</sup> ) |
|--------------------------------|----------------|-----------|----------------------------------------------|
| <i>Typhlodromus pyri</i> ‡     |                | Mortality | No studies submitted                         |
| <i>Aphidius rhopalosiphi</i> ‡ |                | Mortality |                                              |

<sup>1</sup> for preparations indicate whether end point is expressed in units of a.s. or preparation

**Crop and application rate**

| Test substance | Species                      | Effect (LR <sub>50</sub> g/ha) | HQ in-field    | HQ off-field <sup>1</sup> | Trigger |
|----------------|------------------------------|--------------------------------|----------------|---------------------------|---------|
|                | <i>Typhlodromus pyri</i>     |                                | Not calculated |                           | 2       |
|                | <i>Aphidius rhopalosiphi</i> |                                |                |                           | 2       |

<sup>1</sup> indicate distance assumed to calculate the drift rate

**Further laboratory and extended laboratory studies ‡**

| Species                   | Life stage | Test substance, substrate and duration | Dose (g/ha) <sup>1,2</sup> | End point | % effect <sup>3</sup> | Trigger value |
|---------------------------|------------|----------------------------------------|----------------------------|-----------|-----------------------|---------------|
| No studies were submitted |            |                                        |                            |           |                       | 50 %          |

<sup>1</sup> indicate whether initial or aged residues

<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

<sup>3</sup> indicate if positive percentages relate to adverse effects or not

|                           |
|---------------------------|
| Field or semi-field tests |
| Not required              |

**Effects on earthworms, other soil macro-organisms and soil micro-organisms (Annex IIA points 8.4 and 8.5, Annex IIIA, points 10.6 and 10.7)**

| Test organism              | Test substance | Time scale      | End point <sup>1</sup> |
|----------------------------|----------------|-----------------|------------------------|
| Earthworms                 |                |                 |                        |
|                            | a.s. ‡         | Acute 14 days   | No studies submitted   |
|                            | a.s. ‡         | Chronic 8 weeks |                        |
|                            | Preparation    | Acute           |                        |
|                            | Preparation    | Chronic         |                        |
|                            | Metabolite 1   | Acute           |                        |
|                            | Metabolite 1   | Chronic         |                        |
| Other soil macro-organisms |                |                 |                        |
| Soil mite                  | a.s. ‡         |                 | No studies submitted   |
|                            | Preparation    |                 |                        |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology**

| Test organism              | Test substance | Time scale | End point <sup>1</sup> |
|----------------------------|----------------|------------|------------------------|
|                            | Metabolite 1   |            |                        |
| Collembola                 |                |            |                        |
|                            | a.s. ‡         | Chronic    | No studies submitted   |
|                            | Preparation    |            |                        |
|                            | Metabolite 1   |            |                        |
| Soil micro-organisms       |                |            |                        |
| Nitrogen mineralisation    | a.s. ‡         |            | No studies submitted   |
|                            | Metabolite 1   |            |                        |
| Carbon mineralisation      | a.s. ‡         |            | No studies submitted   |
|                            | Metabolite 1   |            |                        |
| Field studies <sup>2</sup> |                |            |                        |
| Not required               |                |            |                        |

<sup>1</sup> indicate where end point has been corrected due to log Pow > 2.0 (e.g. LC<sub>50corr</sub>)

<sup>2</sup> litter bag, field arthropod studies not included at 8.3.2/10.5 above, and earthworm field studies

**Toxicity/exposure ratios for soil organisms****Crop and application rate**

| Crop and application rate  | Test organism | Test substance | Time scale     | Soil PEC <sup>2</sup> | TER | Trigger |
|----------------------------|---------------|----------------|----------------|-----------------------|-----|---------|
| Earthworms                 |               |                |                |                       |     |         |
|                            | a.s. ‡        | Acute          | Not calculated | 10                    |     |         |
|                            | a.s. ‡        | Chronic        |                | 5                     |     |         |
|                            | Preparation   | Acute          |                | 10                    |     |         |
|                            | Preparation   | Chronic        |                | 5                     |     |         |
|                            | Metabolite 1  | Acute          |                | 10                    |     |         |
|                            | Metabolite 1  | Chronic        |                | 5                     |     |         |
| Other soil macro-organisms |               |                |                |                       |     |         |
| Soil mite                  | a.s. ‡        |                | Not calculated |                       |     |         |
|                            | Preparation   |                |                |                       |     |         |
|                            | Metabolite 1  |                |                |                       |     |         |
| Collembola                 | a.s. ‡        |                |                |                       |     |         |
|                            | Preparation   |                |                |                       |     |         |
|                            | Metabolite 1  |                |                |                       |     |         |

to be completed where first Tier triggers are breached

indicate which PEC soil was used (e.g. plateau PEC)

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Ecotoxicology****Effects on non target plants (Annex IIA, point 8.6, Annex IIIA, point 10.8)**

Preliminary screening data

|                           |
|---------------------------|
| No studies were submitted |
|---------------------------|

Laboratory dose response tests

| Most sensitive species | Test substance | ER <sub>50</sub> (g/ha) <sup>2</sup><br>vegetative vigour | ER <sub>50</sub> (g/ha) <sup>2</sup><br>emergence | Exposure <sup>1</sup><br>(g/ha) <sup>2</sup> | TER | Trigger |
|------------------------|----------------|-----------------------------------------------------------|---------------------------------------------------|----------------------------------------------|-----|---------|
| Not calculated         |                |                                                           |                                                   |                                              |     |         |

<sup>1</sup> explanation of how exposure has been estimated should be provided (e.g. based on Ganzelmeier drift data)<sup>2</sup> for preparations indicate whether dose is expressed in units of a.s. or preparation

Additional studies (e.g. semi-field or field studies)

|              |
|--------------|
| Not required |
|--------------|

**Effects on biological methods for sewage treatment (Annex IIA 8.7)**

| Test type/organism    | end point |
|-----------------------|-----------|
| Activated sludge      | -         |
| <i>Pseudomonas sp</i> | -         |

**Ecotoxicologically relevant compounds** (consider parent and all relevant metabolites requiring further assessment from the fate section)

| Compartment |                 |
|-------------|-----------------|
| soil        | calcium carbide |
| water       | calcium carbide |
| sediment    | calcium carbide |
| groundwater | calcium carbide |

**Classification and proposed labelling with regard to ecotoxicological data (Annex IIA, point 10 and Annex IIIA, point 12.3)**

|                  |                          |
|------------------|--------------------------|
| Active substance | RMS/peer review proposal |
|                  | R51/53                   |
| Preparation      | RMS/peer review proposal |
|                  | R51/53                   |

‡ End point identified by the EU-Commission as relevant for Member States when applying the Uniform Principles

| Rapporteur Member State | Month and year | Active Substance (Name) |
|-------------------------|----------------|-------------------------|
| Portugal                | June 2007      | Calcium carbide         |

**Appendix 1– Used compound code(s) in the list of end points**

| Code/Trivial name | Chemical name | Structural formula |
|-------------------|---------------|--------------------|
|-------------------|---------------|--------------------|

WARNING: This document forms part of an EC evaluation data package and should not be read in isolation. Registration must not be granted on the basis of this document.

## **CALCIUM CARBIDE**

### **LEVEL 3**

Proposed decision with respect to the application for  
inclusion of the active substance in Annex I

### 3 Proposed decision with respect to the application for inclusion of the active substance in Annex I

#### 3.1 Background to the proposed decision

Calcium carbide formulated as PRONTOX-vole gas (PRONTOX Wühlmausgas) is a gas generating product containing 80% w/w calcium carbide and minor quantities (0.025-0.05% w/w) of calcium phosphide. It is applied in granular form as a repellent for voles (*Arvicola terrestris*) and moles (*Talpa europaea*). to be used as repellent against voles and moles in meadows, fruit, vegetable, field and ornamental cultivation and in house and allotment areas. The solid product is to be placed in the holes made by the pests.

The useful recommended mode of application is at rate of 10g/tunnel for voles and at rate of 20g/burrow for moles of technical calcium carbide. Depending on the infestation level, the application rate should range between 2.5-10kg/ha of technical calcium carbide.

For the proposed use (repellent), technical calcium carbide needs to contain calcium phosphide (0.02%w/w) for the production of phosphine in the presence of moisture. Phosphine has a garlic odour and is in fact the repellent active substance.

The acceptability of the technical specification depends on the submission of validated analytical methods for the determination of calcium carbide, calcium phosphide and all significant impurities present in the analytical profile.

Detailed investigations of calcium carbide metabolism based on the hydrolysis to calcium hydroxide and acetylene were not considered to be required, since dietary exposure of humans does not occur in view of the lack of appreciable residues according to the use of the substance as repellent. In the use of technical calcium carbide as a repellent against voles and moles, the granulate is introduced into the animal's burrows where it is decomposed to calcium hydroxide and acetylene by ground humidity. Additionally, odour-intensive phosphine gas arises from hydrolysis of the very small amounts of calcium phosphide present on the technical material. The calcium hydroxide remaining in the ground binds with carbon dioxide in the air and forms calcium bicarbonate in the first stage, which later partly changes into calcium carbonate. Both substances do not possess any toxic properties. From the facts presented, it follows that the calcium carbide itself, as well as its decomposition product acetylene, calcium hydroxide and phosphine do not enter into the food chain. No ADI, AOEL or ARfD were allocated for calcium carbide, as they were not considered necessary.

PRONTOX Wühlmausgas is identical to technical calcium carbide. Studies attempted to be carried out with the a.s. resulted in a measured pH of 12.48 with a 1% solution in deionised water of calcium carbide, accordingly, no experiment was undertaken for humane reasons on live animals and a classification as corrosive (R35) of the substance was proposed, which is in accordance with human experience. According to human experience also, a classification with R37 is proposed.

PRONTOX Wühlmausgas (calcium carbide) is introduced into the target animals underground runs and tunnels by means of a spoon or another aid. The spoon should be designed to both an applicator and a dosage measuring system to eliminate operator exposure. Underground, the evolution of acetylene and phosphine is not abrupt, but depends on the progressive absorption of soil moisture. Since phosphine is heavier than air, it remains within the target animals burrows underground, and because the entrances to the burrow system are closed, the gas ultimately diffuses into the surrounding soil, with no more than trace quantities reaching the surface, well away from the respiration zone of operators or bystanders. Skin contact with PRONTOX Wühlmausgas is effectively prevented by wearing general-purpose protective clothing, gloves and eye/face

protection when applying/handling the product ready for application.

Calcium carbide is not intended for direct application to growing crops, no residues in plants or in plant food stuffs are to be expected and calcium carbide, used as repellent, does not enter in the human food chain.

No information was submitted by the applicant on section 5 on environmental fate and behaviour and section 6 on ecotoxicology. Only five studies with low reliability were submitted. This report was based on the RMS assessment of the applicant dossier (from Doc. A to J, Tier III chapter 1 to 4 and 7) and on research.

Calcium carbide is very reactive in presence of water, soil moisture or air humidity, with degradation into calcium hydroxide, acetylene gas and phosphine gas. Considering the intended use, only soil compartment will be exposed to this substance or degradation products. In soil, underground, calcium carbide reacts with soil moisture into calcium hydroxide that reacts with carbon dioxide to calcium bicarbonate and calcium carbonate, other calcium carbide impurities as carbon aluminium oxide, iron oxide and silicon dioxide are ubiquitous and stable in the soil. Phosphine and acetylene gas will be trapped underground. Phosphine released in small quantities is adsorbed and degraded in soil into phosphates, used as trace nutrients for plants. Acetylene released underground inhibits the activity bacteria involved in soil nitrification. The slow down of nitrification process may represent an indirect benefit in particular in agricultural soils exposed to successive fertilization. The incorporation of acetylene in soil has been pursued as a strategy to improve recovery of fertilizer nitrogen (N) by crops through lowering losses by leaching of nitrate or denitrification in order to benefit yields and the environment.

Underground terrestrial organisms as mammals, earthworms, arthropods and micro-organisms can be directly exposed to the products and those degradation products. Birds and mammals can also be indirectly exposed by ingestion of contaminated food. No toxicological studies were submitted for soil organisms. Regarding the calcium carbide and degradation products properties, the only substance expected to cause adverse effects to those organisms is phosphine, a very powerful poison, acting by inhalation in the respiratory chain. Phosphine toxicity to soil organisms was considered an issue, and in absence of any available study RMS tried to demonstrate that the low content of calcium phosphide present in the technical product (0.025-0.05 w/w) was low enough to don't cause adverse effects to soil organisms, when phosphine is released. Considering the fate and behaviour of phosphine in soil risk to terrestrial organisms can be considered low.

Only toxicological studies on aquatic organisms were presented. Daphnia were the most susceptible organisms. An  $LC_{50}$  (96h) static > 50 mg/l calcium carbide was considered for fish. An  $EC_{50}$  (48h) of 4.62 mg/l calcium carbide was estimated for Daphnia. For algae an  $E_bC_{50}$  of 12.4 mg/l and an  $E_rC_{50}$  46.5 mg/l calcium carbide. The calcium carbide technical, as well as the product PRONTOX Wühlmausgas, since product is the technical active substance unformulated, should be classified as Toxic to aquatic organisms.

Regarding the intended uses of the product it is expected that aquatic organisms, and other non target organisms that live above soil, birds, mammals, bees or other arthropods, would not be exposed to the active substance or degradation products. So those non target organisms would not be at risk.

From the efficacy point of view, PRONTOX Wühlmausgas is considered effective at the application rates proposed.

### 3.2 Proposed decision concerning inclusion in Annex I

**3.3 Rational for the postponement of the decision to include the active substance in Annex I, or for the conditions and restrictions to be associated with a proposed inclusion in Annex I, as appropriate**

Not applicable.

The information in section 3.2 has been removed upon request by the EU Commission as it relates to risk management recommendations or proposals.

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## **CALCIUM CARBIDE**

### **LEVEL 4**

Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I

#### **4 Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with the proposed inclusion in Annex I**

##### **4.1 Identity of the active substance**

The acceptability of the technical specification depends on the submission of validated analytical methods for the determination of calcium carbide, calcium phosphide and all significant impurities present in the analytical profile. See 4.5 below.

##### **4.2 Physical and chemical properties of the active substance**

Annex II A

2.1.1 Melting point of purified calcium phosphide

2.2 Relative density of purified calcium phosphide

2.3.1 Vapour pressure of purified calcium phosphide

2.4 Appearance of purified calcium phosphide

2.11.1 Flammability of technical calcium carbide must be determined according to EEC A12 method.

Annex III A

2.7.1 Study on accelerated storage stability with control analysis of calcium phosphide

2.7.3 Study on storage stability at ambient temperature with control analysis of calcium phosphide

##### **4.3 Data on application and further information**

No further data required.

##### **4.4. Classification, packaging and labelling**

No further data required.

##### **4.5 Methods of analysis**

Annex IIA (for each source)

4.1.1 Method must be described in full for the determination of calcium phosphide and calcium carbide in the technical calcium carbide

4.1.2 Methods must be described in full for determination of all significant impurities in the technical calcium carbide

4.1.3 Specificity, linearity, accuracy and repeatability for all the required methods.

##### **4.6. Toxicology and metabolism**

No further data required.

##### **4.7 Residue data**

No data required.

**4.8 Environmental fate and behaviour**

No requests.

**4.9 Ecotoxicology**

No requests.

**4.10 Efficacy**

No further data required.

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